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IN THE EYE OF THE PATENTHOLDER:  
DR. SAMUEL PALLIN AND THE CHEVRON INCISION

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Badrinath Rengarajan

Yale University

1999

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Signature of Author

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In the Eye of the Patentholder: Dr. Samuel Pallin and the Chevron Incision

A Thesis Submitted to the  
Yale University School of Medicine  
in Partial Fulfillment of the Requirements for the  
Degree of Doctor of Medicine

by  
Badrinath Rengarajan  
1999

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## IN THE EYE OF THE PATENTHOLDER: DR. SAMUEL PALLIN AND THE CHEVRON INCISION.

Badrinath Rengarajan (Sponsored by Frederic L. Holmes). Section of the History of Medicine, Yale University School of Medicine, New Haven, CT.

This project describes the controversy surrounding the patenting of medical and surgical methods by telling the story of Dr. Samuel Pallin's 1993 lawsuit against fellow ophthalmologist Dr. Jack Singer for infringing the patent on his chevron sutureless incision technique. This project seeks to comment on the effects of Dr. Pallin's lawsuit on his patent and on the medical profession, to understand the basis for banning medical procedure patents (or their enforcement), and to understand why participants in this controversy behaved as they did. Methods included interviewing key participants and examining historical literature, legal articles, court documents, and medical texts.

Pallin sued Singer because Singer's incision technique was most similar to his own work, and a successful suit against Singer would clear the path to enforce his patent against other physicians. However, the sutureless incision techniques of other surgeons predated Pallin's patented work, and the chevron incision technique is rendered obvious to an ordinary ocular surgeon when one takes into account the full body of state-of-the-art knowledge at the time Pallin claims to have invented his method. Thus, his patent was effectively invalidated. The AMA and other medical societies feared that patents on medical methods would lower the quality of patient care, compromise physician autonomy and the doctor-patient relationship, hinder the dissemination of knowledge, and increase health care costs and litigation. They lobbied Congress to ban the patenting of medical methods while continuing to allow the patenting of medical products. In 1996, perhaps to placate the medical community, Congress banned the enforcement of medical method patents against health care providers. However, the concerns of the opponents of medical method patents could have been allayed with changes in practices at the U.S. Patent and Trademark Office. Although Pallin's lawsuit against Singer informs our understanding of other medical method patent controversies, medical method patents are not likely to be a significant problem.



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^ vs. ○

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My greatest thanks goes to the Office of Student Research of the Yale School of Medicine for funding portions of this project; Dr. Maria Trumpler for thoughts on the initial proposal for this project; Dr. Carolyn Cooper for editing my work and stimulating my thinking; and Professor Frederic Holmes, Chairman of the Section of History of Medicine of Yale University, for sponsoring my project.





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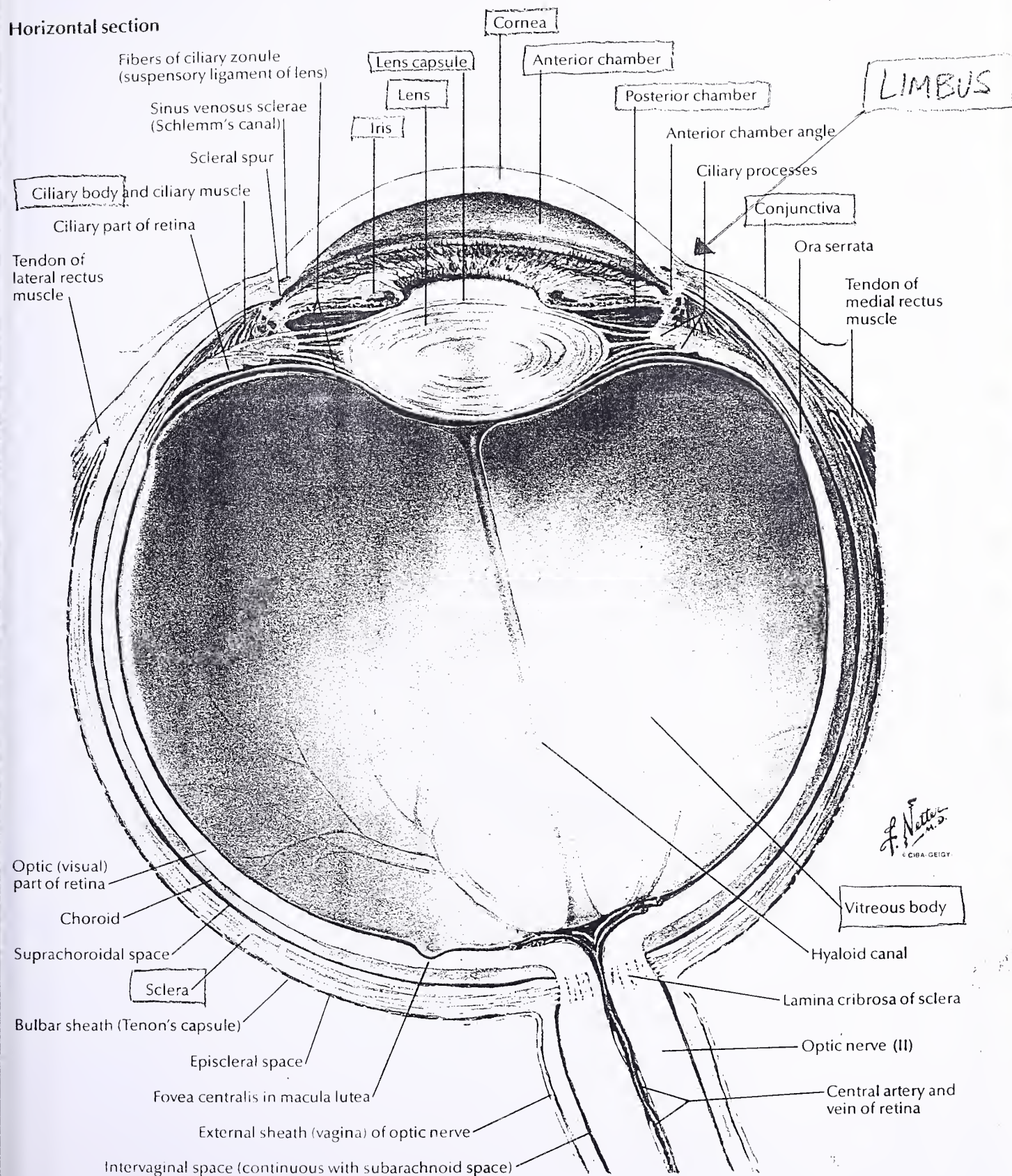
Figure 1 – Howard Fine's View of Patent Claim 1 and Incision Shapes

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Chronology



### Horizontal section







# ANATOMY OF EYE

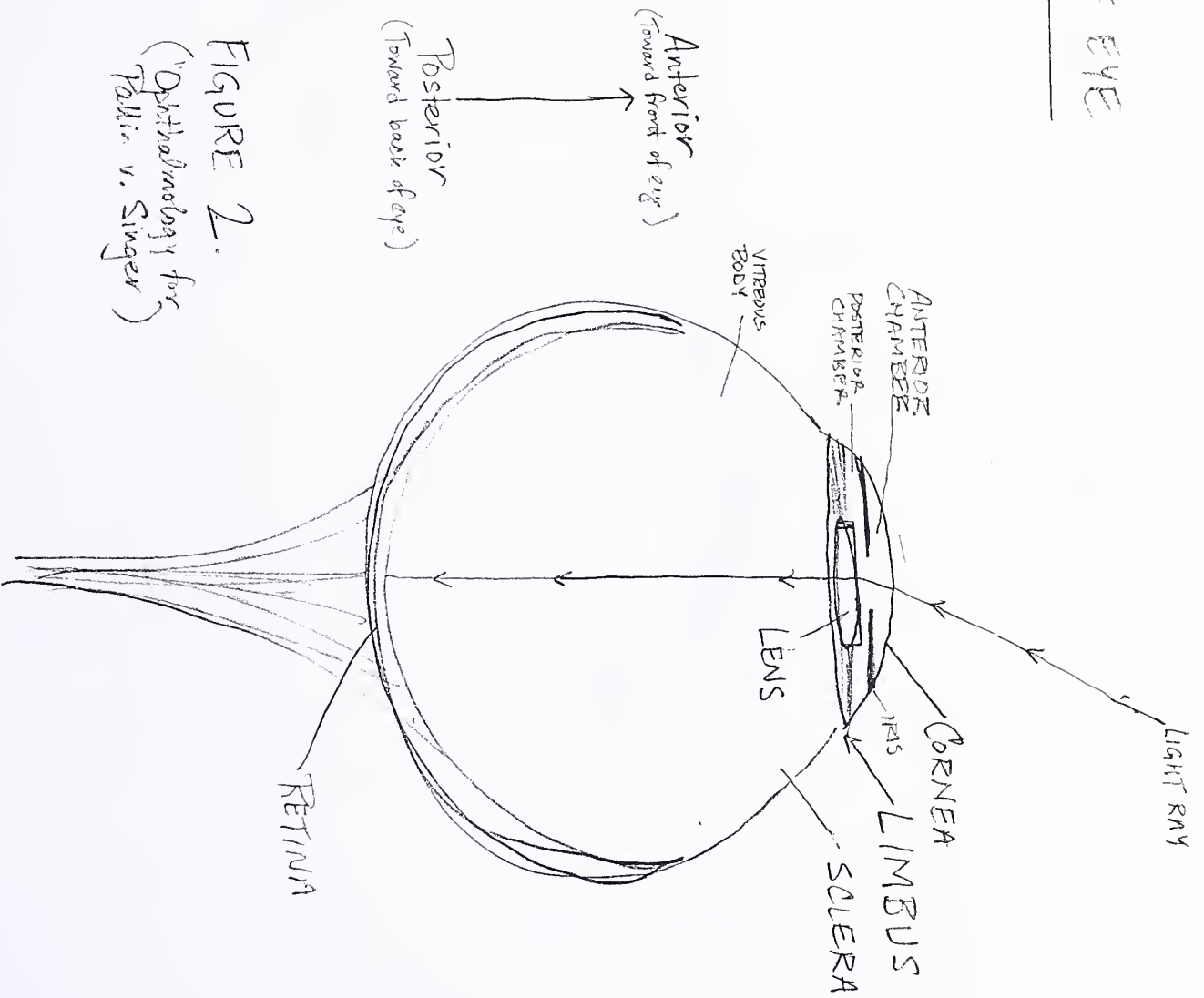


FIGURE 2.  
("Ophthalmology for  
Fallis v. Singer")



# BASIC STEPS OF CATARACT SURGERY

1. Make incision
2. Enter anterior chamber
3. Remove lens
4. Implant IOL
5. Close incision

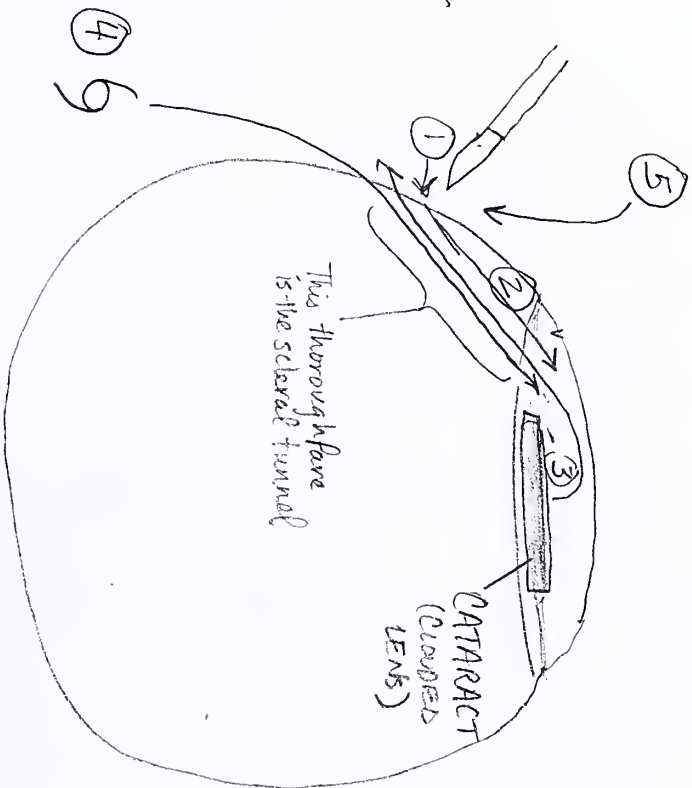


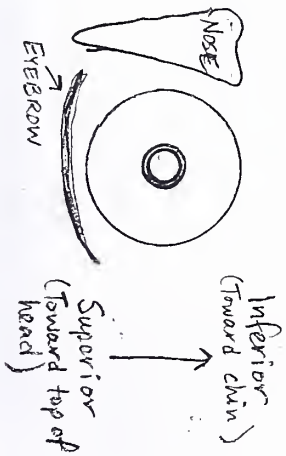
FIGURE 3

("Ophthalmology for Fallin v. Singer")

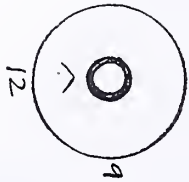


# INCISION SHAPES

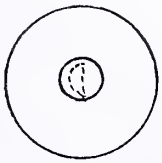
• Surgeon's view  
(upside-down  
view of the  
right eye)



• Incision at  
12 o'clock position

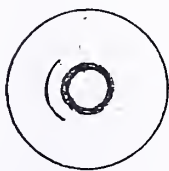


• Classic vonGraefe  
incision  
(no longer used)



Incision = dotted line

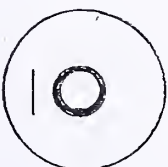
• Traditional  
curvilinear  
(aka, "smile")



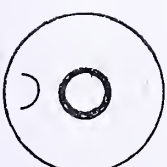
• Radial transverse



• Straight line



• Frown



• Chevron



Trend toward  
incision extremities  
curving away from  
limbo.

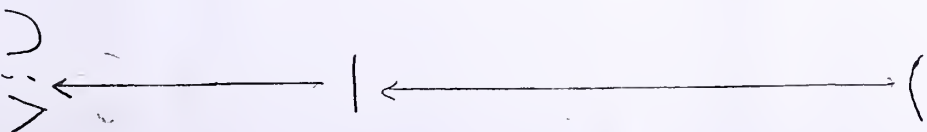


FIGURE 4 ("Ophthalmology for Pallin v. Singer")



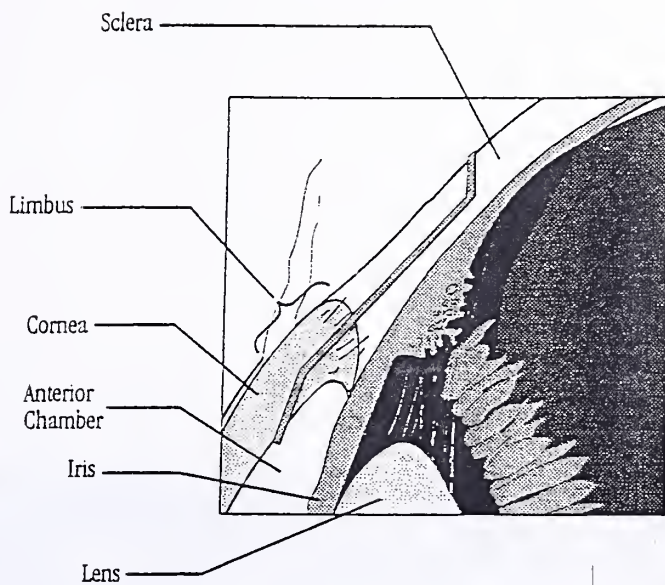


FIGURE 5  
("Ophthalmology for Pallin v. Singer")  
**THREE STEP CORNEAL -  
LIP INCISION**

Source: Defense documents in Pallin v. Singer





## THREE-PLANE INCISION

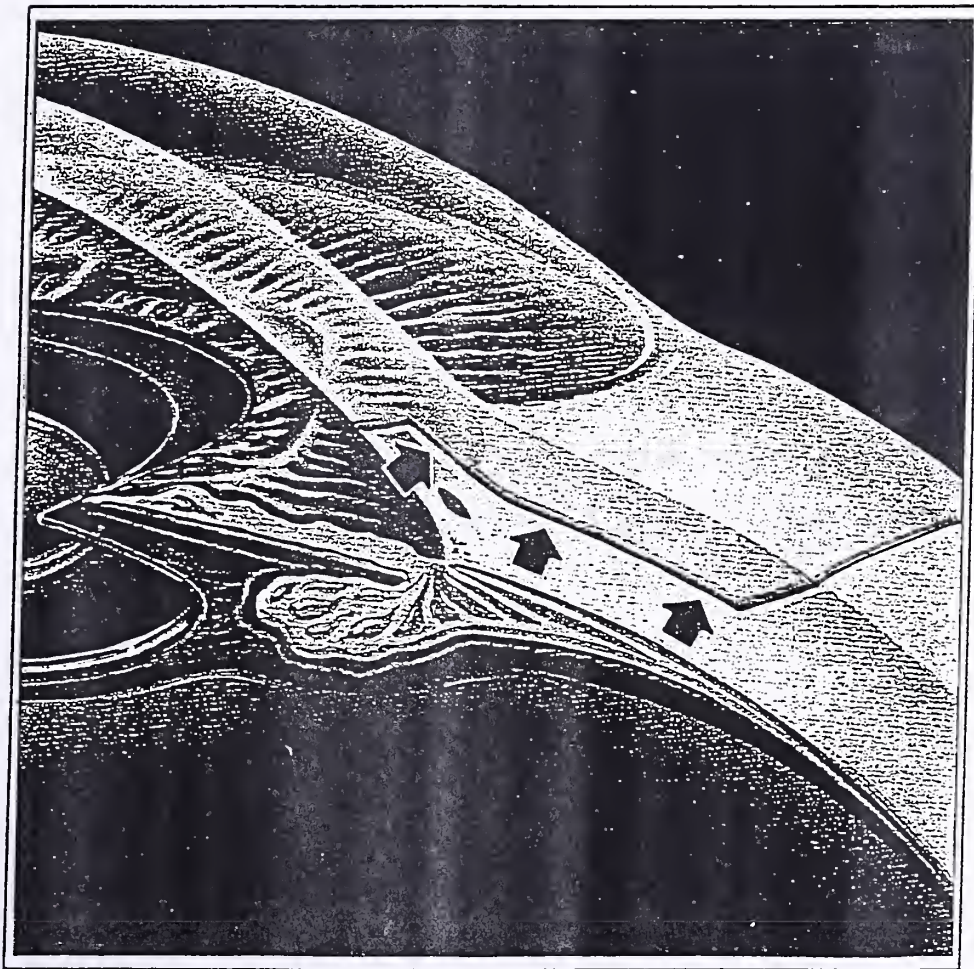


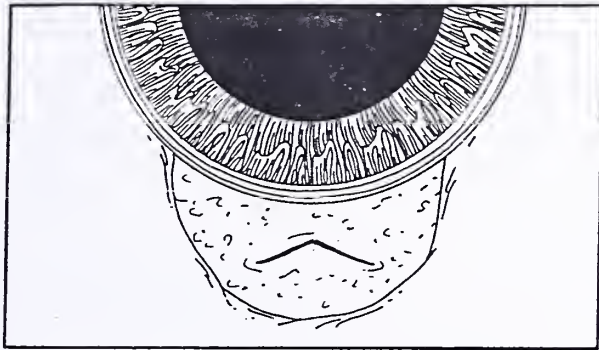
FIGURE 6 ("Ophthalmology for Pallin v. Singer")

Source: Sutureless Cataract Surgery (Gills, J., Martin, R., and Sanders, D. (eds)), Slack, Inc, 1992, in defense documents in Pallin v. Singer

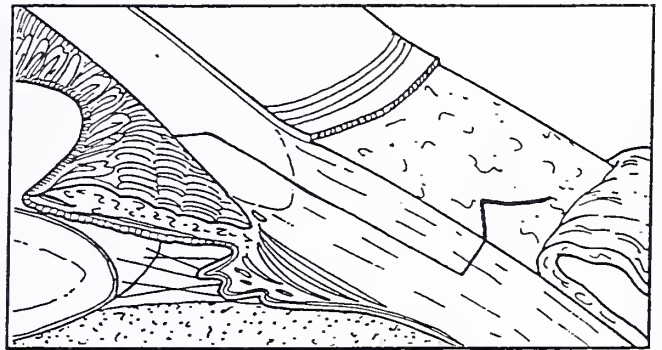


## VIEW OF SCLERAL INCISION

FIGURE 7 ("Ophthalmology for Pallin v. Singer")



Front view of scleral incision  
(chevron-shaped)



Three-dimensional cross-sectional view

Source: Defense documents in *Pallin v. Singer*



SELECTED MEDICAL AND SURGICAL METHOD PATENTS,  
 1846-1993

TABLE 1

U.S. Patent No.	Issue Date	Subject
4,848	1846	Surgical anesthesia with ether
1,547,369	1925	Inoculating patients against scarlet fever
2,008,526	1935	Treating hepatomegaly with electrical current
2,098,295	1937	Inducing fever in humans to treat disease
2,322,245	1943	Method of transcutaneous injection
2,601,204	1952	Anticoagulating blood with coumadin
3,043,309	1962	Endoscopic intestinal intubation with external magnetic direction
3,092,111	1963	Therapeutic desquamation of skin with abrasive paste
3,112,743	1963	Setting a fractured bone by injecting rapidly setting viscous material into the fracture site
3,117,571	1964	Modifying neuronal activity by external application of ultrasonic irradiation
3,118,449	1964	Process of patching horse hooves by shoeing and applying rubber cement externally
3,120,227	1964	Method of obtaining a fetal electrocardiogram by introducing electrode into vagina and through skin of fetus
3,140,709	1964	Process of reducing patient discomfort by introducing acoustic energy into ear of patient
3,141,459	1964	Method of wrapping circumferential head band-age
3,247,841	1966	Method of diagnosing colon lesions by introducing silicone rubber into the colon, allowing it to set, and removing it by defecation
3,260,261	1966	Reducing chafing of adjacent skin folds by placing a desiccant between the skin folds
3,352,303	1967	Lysing blood clots by applying sonic energy externally over the clot
3,358,688	1967	Preparing a skin graft by making parallel columns of slits, with the slits in adjacent columns offset, so that graft expands into a mesh of skin ribbons
3,366,110	1968	Treating burns with brine solution

SELECTED MEDICAL AND SURGICAL METHOD PATENTS,  
 1846-1993

TABLE 1--Continued

U.S. Patent No.	Issue Date	Subject
3,406,681	1968	Reflecting polarized light off the iris and analyzing light reflected back through the cornea to detect eye disease
3,420,233	1969	Treating cutaneous ulcers by applying gold leaf material
3,420,237	1969	Method of treating severe epistaxis by introducing gauze into nasal passage over a catheter
3,422,813	1969	Sterilizing males by surgically placing plug in vas deferens
3,492,989	1970	Treating abnormalities of binocular vision by simultaneously stimulating the eyes at preselected optimal frequency
3,654,914	1972	Cosmetic surgery process of removing subcutaneous tissue and fat from redundant tissue, homogenizing the tissue and fat, and injecting the mixture under tightened skin
3,710,789	1973	Method of repairing bone fractures by placing wire mesh around fracture
3,712,291	1973	Treating iron deficiency by administering iron sublingually or rectally
3,776,230	1973	Method of correcting refractive errors of eye by applying heat to cornea and reshaping convex curvature of cornea with mold
3,782,387	1974	Method of making skin grafts by blistering the donor site
3,789,833	1974	Examining human heart with ultrasound waves
3,872,859	1975	Stimulating hair follicles with electrodes
3,875,928	1975	Surgical method of treating sliding esophageal hernia by placing prosthesis around distal esophagus
3,884,236	1975	Treating glaucoma with intraocular laser
3,941,136	1976	Inducing urination, defecation or erection by applying electrical pulses externally the pubic area





TABLE 1—Continued

SELECTED MEDICAL AND SURGICAL METHOD PATENTS,  
1846-1993

U.S. Patent No.	Issue Date	Subject
3,942,519	1976	Surgical method of cryogenic cataract removal
3,946,725	1976	Assessing depth of anesthesia by monitoring EKG R waves
4,002,169	1977	Method of performing cataract removal through a needle that masticates cataract and withdraws it through needle
4,003,374	1977	Method of preventing venous thrombosis during anesthesia by periodically dorsiflexing a foot of the patient
4,004,577	1977	Algorithm for pre-hospital treatment of myocardial infarction
4,004,592	1977	Method of transplanting human hair by thrusting the hair root into the epidermis with a needle
4,009,260	1977	Process of increasing Y sperm by controlling temperature of semen specimen
4,073,289	1978	Method of male contraception by applying ultrasound externally to scrotum
4,078,564	1978	Method of removing cataracts by injecting lens digesting enzymes into the eye, and removing digested lens
4,127,118	1978	Method of treating male impotence by injecting vasodilators into penis
4,339,434	1982	Method of increasing incidence of female offspring
4,399,813	1983	Method of removing prosthesis embedded in skeletal bone
4,986,274	1991	Fetal anatomic sex assignment by ultrasonography during early pregnancy
5,179,964	1993	Method of closing a surgical incision with parallel rows of staples

This table includes representative patents listed in the Patent Office Official Gazette. Patent listings are not proportionate to the number of patents granted during particular time periods. Patents granted in the period 1960-1980 have been emphasized to demonstrate that medical and surgical procedure patents are not a recent phenomenon.

The great majority of patent applications are filed on minor scientific advances (see Table 1). Nonetheless each application must be prosecuted through the Patent Office, often at an expense of many thousands of dollars. The Patent Office has erected numerous internal barriers to successfully patenting therapeutic inventions, such as strict requirements for proving efficacy of a claimed therapeutic method.<sup>31</sup> Moreover, the requirement that an invention must be a "nonobvious" advance to be patentable is particularly strictly applied in all the biological examining groups. The likelihood that a biological patent application will successfully issue as a patent is about one-half of the likelihood of success in conventional mechanical and electrical cases. Many biological patents that emerge from this rigorous patenting process are narrow in scope, difficult to enforce, and unlikely to cover anything that will be widely or successfully used in medicine.<sup>32</sup>

Even if all these obstacles are overcome, and a patent of reasonable scope issues on an important therapeutic advance, then the patent must be licensed or enforced. The problems of contemporary patent enforcement are magnified many times in the context of medical and surgical procedure patents. Patent enforcement is not an insurmountable problem among large corporations that only have a few competitors, all of whom can be licensed under the patent or sued to stop any infringing use. Infringement of patented devices or drugs is also relatively easily detected by the presence of infringing products sold on the open market. A single injunction issued by a court can stop the production of infringing products from a mass producing infringer. A medical process patent, however, is potentially infringed by hundreds of thousands of individual physicians. Detecting the infringement is often nearly impossible. It would occur intermittently in the privacy of individual physicians' offices across the country, within the context of a confidential doctor-patient relationship, and often with no record of the infringement. Litigating the patent against hundreds or thousands of defendants would be logistically difficult and financially unfeasible. The damages that could be collected against the scattered individual defendants would be unlikely to justify the extraordinary expense and risk of patent infringement litigation. These economic realities of modern American patent infringement litigation do not suggest that a wave of medical procedure patent litigation is about to sweep over the country.

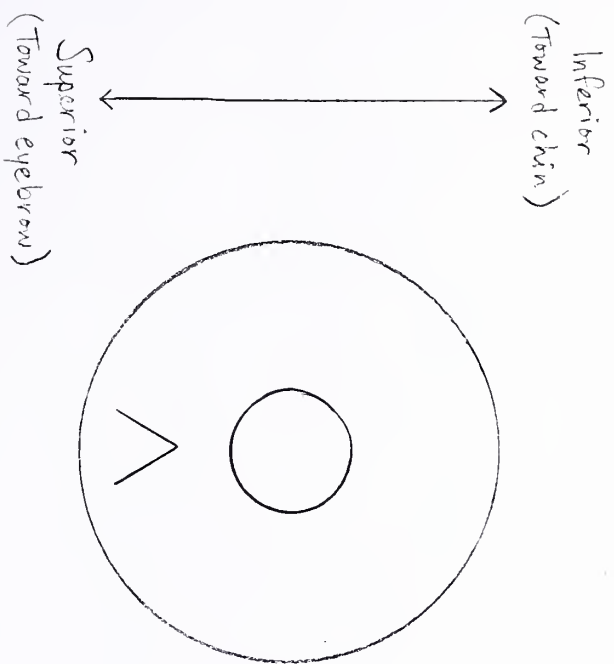
<sup>31</sup> Noonan, *supra* note 25, at 276-279.

<sup>32</sup> J. KAVYTON, DESIGNING AROUND VALID US PATENTS, v. 1, preface.



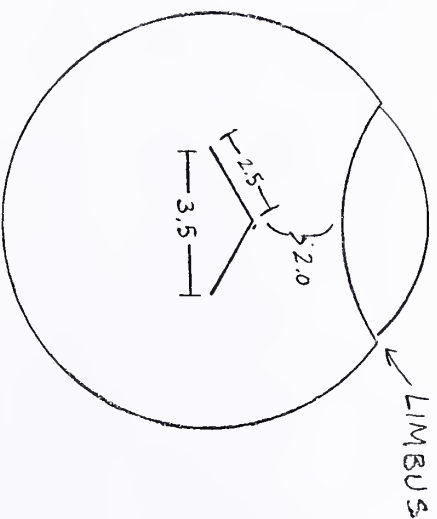


# CHEVRON INCISION

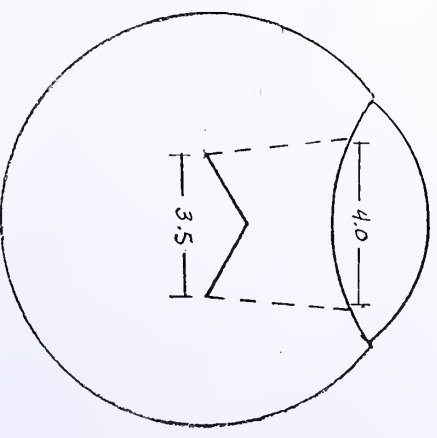


Eye tilted  
90° inferiorly

Incision Dimensions



Tunnel Dimensions

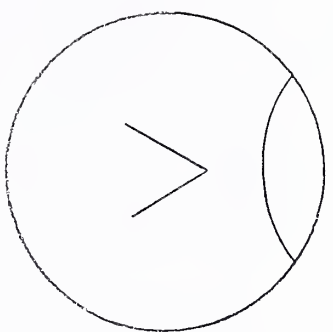


Note: All measurements in millimeters

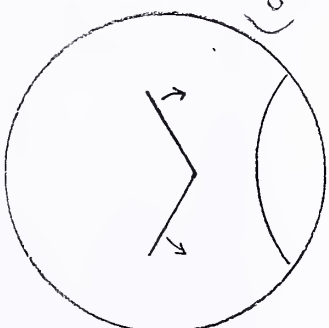
FIGURE 1 ("Pallin's Invention and Patent")



# PALLIN'S THEORY OF SELF-SEALING



Increase in  
Intraocular Pressure (IOP)  
at end of procedure



↑ IOP

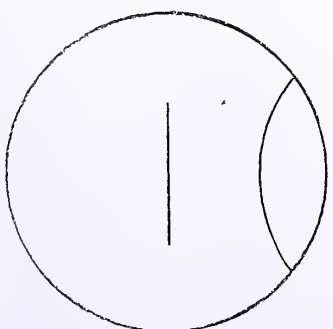
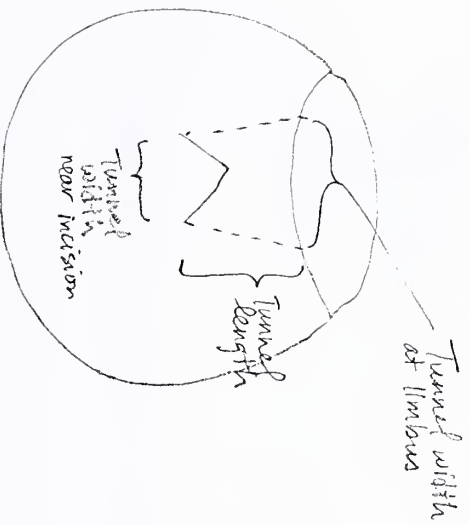


FIGURE 2 ("Pallin's Invention and Patent")



# PALLIN'S CONCEPTION OF EFFECT OF INCISION SHAPE ON SEALING

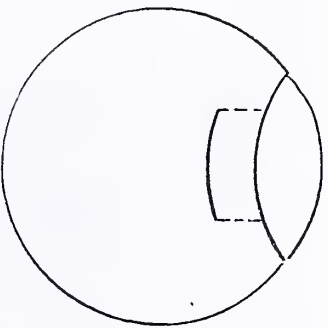


Relative turned width-length ratios

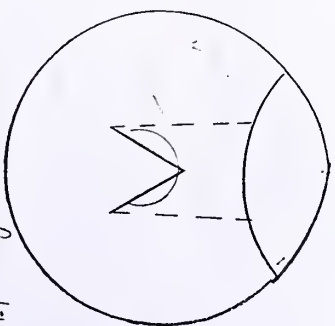
- $W > L$
- $W \approx L$
- $W < L$

Sealing tendency

- Low
- Medium
- High



Curved toward limbus  
→ Effective L:W ratio is low



Diverging away from limbus  
→ Effective L:W ratio is higher, because extremities of incision are farther from limbus

FIGURE 3 ("Pallin's Invention and Patent")





CONTENTIOUS PATENT TEXT  
U.S. Patent #5,080,111

Claims at issue:

• *Claim 1*: A method of making a substantially self-sealing episcleral incision comprising; providing incision making means; making an incision in the sclera with said means; and said incision having an appropriate central point 1.5 to 3.0 millimeters posterior to the limbus wherein portions of said incision extend away from said approximate central point and extend laterally away from the curvature of said limbus

• *Claim 7*: The method of claim 1 further including making an incision having a curvilinear configuration

• *Claim 22*: A method of making a substantially self-sealing episcleral incision comprising; providing incision making means; making an incision in the sclera with said means; and said incision having a curvilinear configuration and an approximate central point 1.5 to 3.0 millimeters posterior to the limbus, portions of said incision extending from said approximate central point further extending laterally away from the curvature of said limbus

• *Claim 28*: The method of claim 22 further including forming a scleral tunnel from the incision extending to the anterior chamber of the eye

Other contentious patent text:

• *The nature of the invention*: A substantially self-sealing episcleral incision having an approximate central point 1.5 to 3.0 millimeters posterior to the limbus. Portions of the incision extending from the approximate central point extend laterally away from the curvature of the limbus. The configuration of the self-sealing incision allows the incision to seal as the eye is inflated following surgery, and therefore requires no sutures for sealing. Accordingly, the probability of astigmatism is eliminated or greatly reduced and the reliance on sutures is eliminated. [Emphasis mine] (Abstract)

• *Use of a suture*: Further, even larger lens implants of up to 6 millimeters in diameter may be inserted through larger incisions. . . . although a single suture may occasionally be required for complete sealing. [Emphasis mine] (column 4, lines 41-45)

• *The meaning of "substantially self-sealing"*: The configurations wherein linear portions...of incision...and lateral portions...of incision...extend laterally away from the curvature of limbus...enable incisions...to be substantially self-sealing. When eye...is inflated following surgery, the force vectors acting on incisions...induce the closure of scleral tunnel...so that incisions...become water-tight and require no sutures for sealing. (column 4, lines 9-16)



# PATENT FIGURES 3 AND 4

14 - Sclera  
22a - Incision

36 - Two substantially  
linear portions

38 - Apex

42 - Approximate  
central point

44 - Lateral portions

FIG. 3

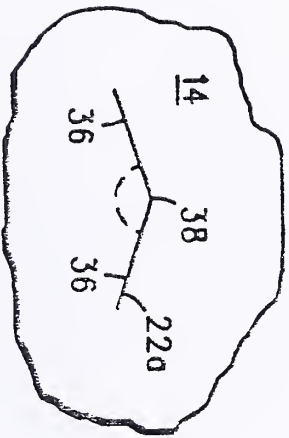


FIG. 4

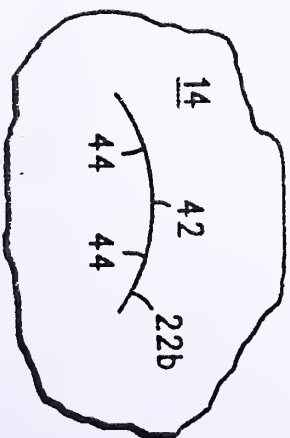
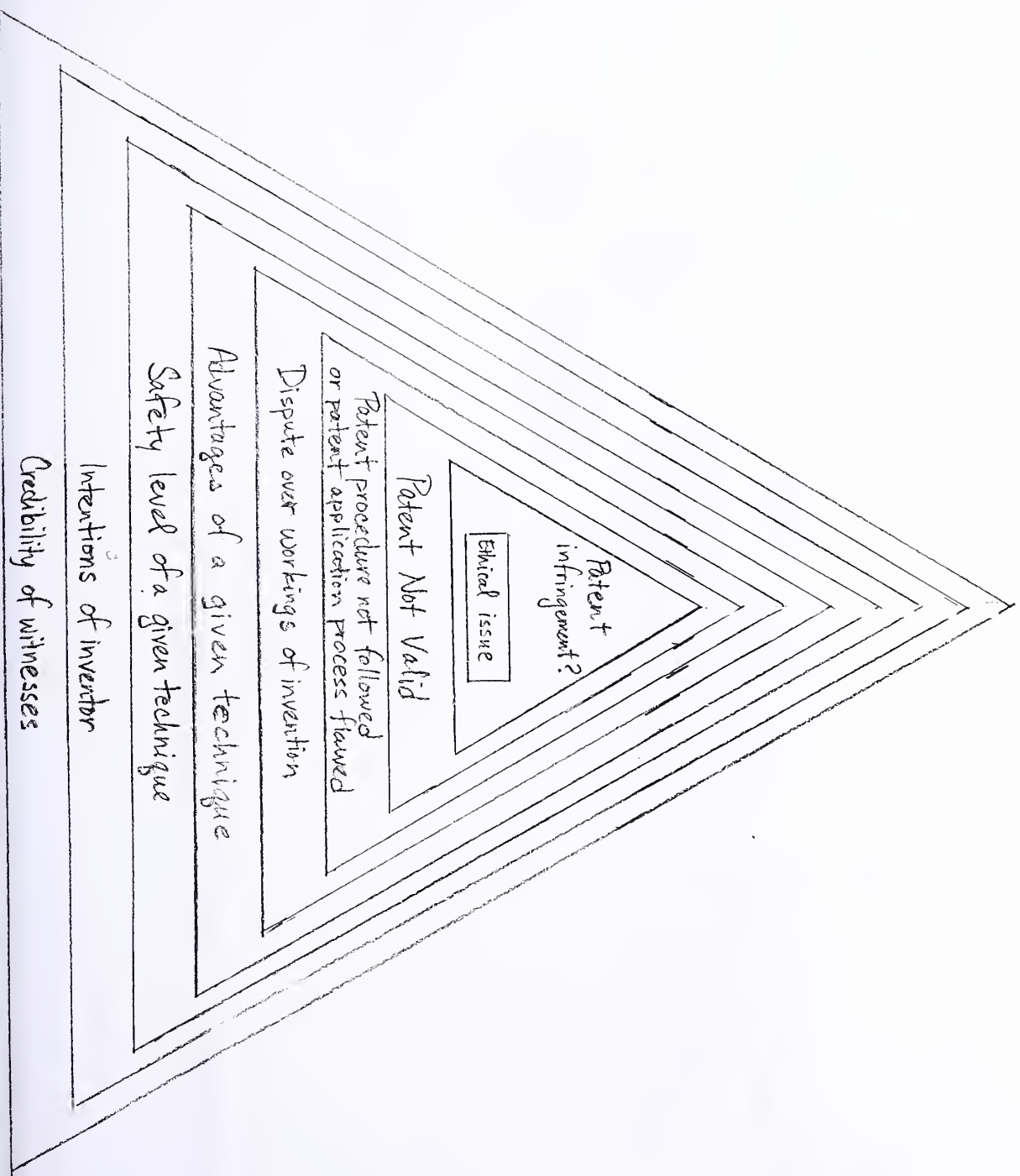


FIGURE 4 ("Pallin's Invention and Patent")

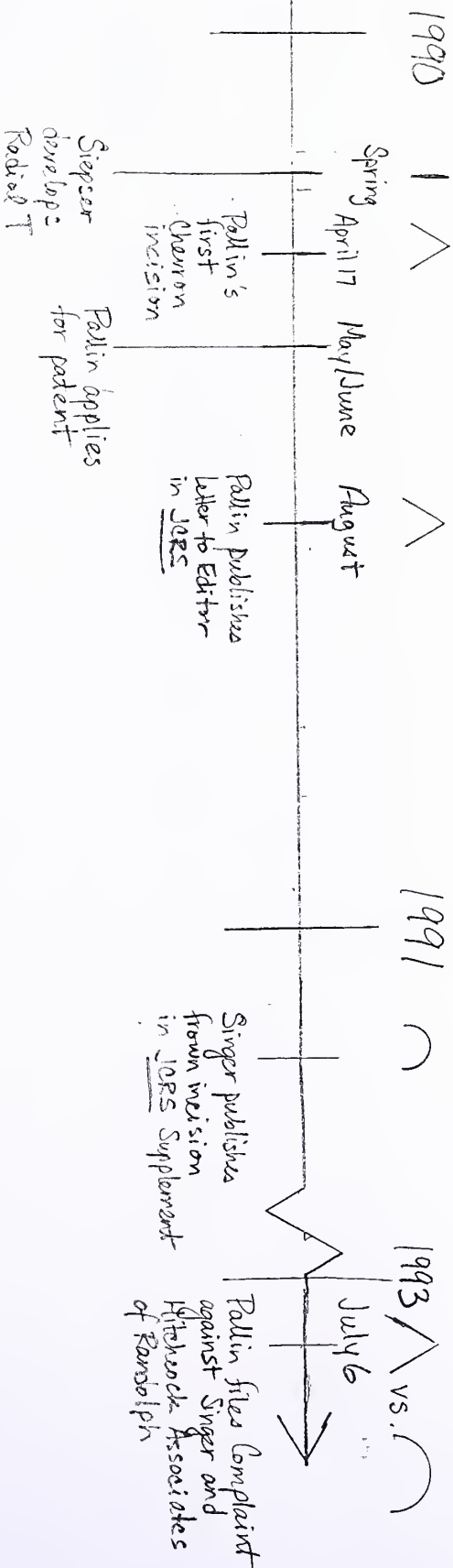


# DEFLECTION OF MAIN ISSUE





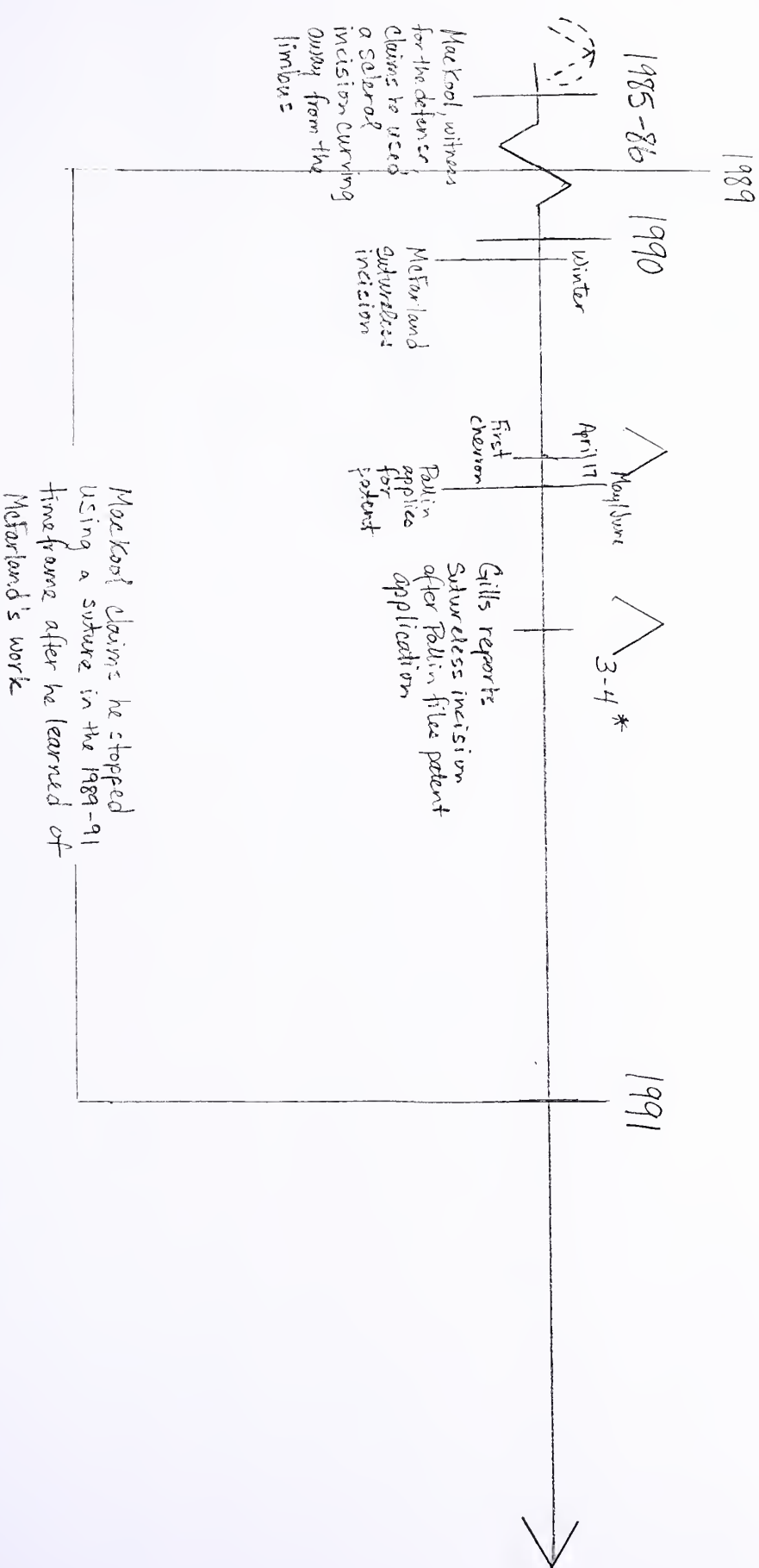
# TIMELINE 1A







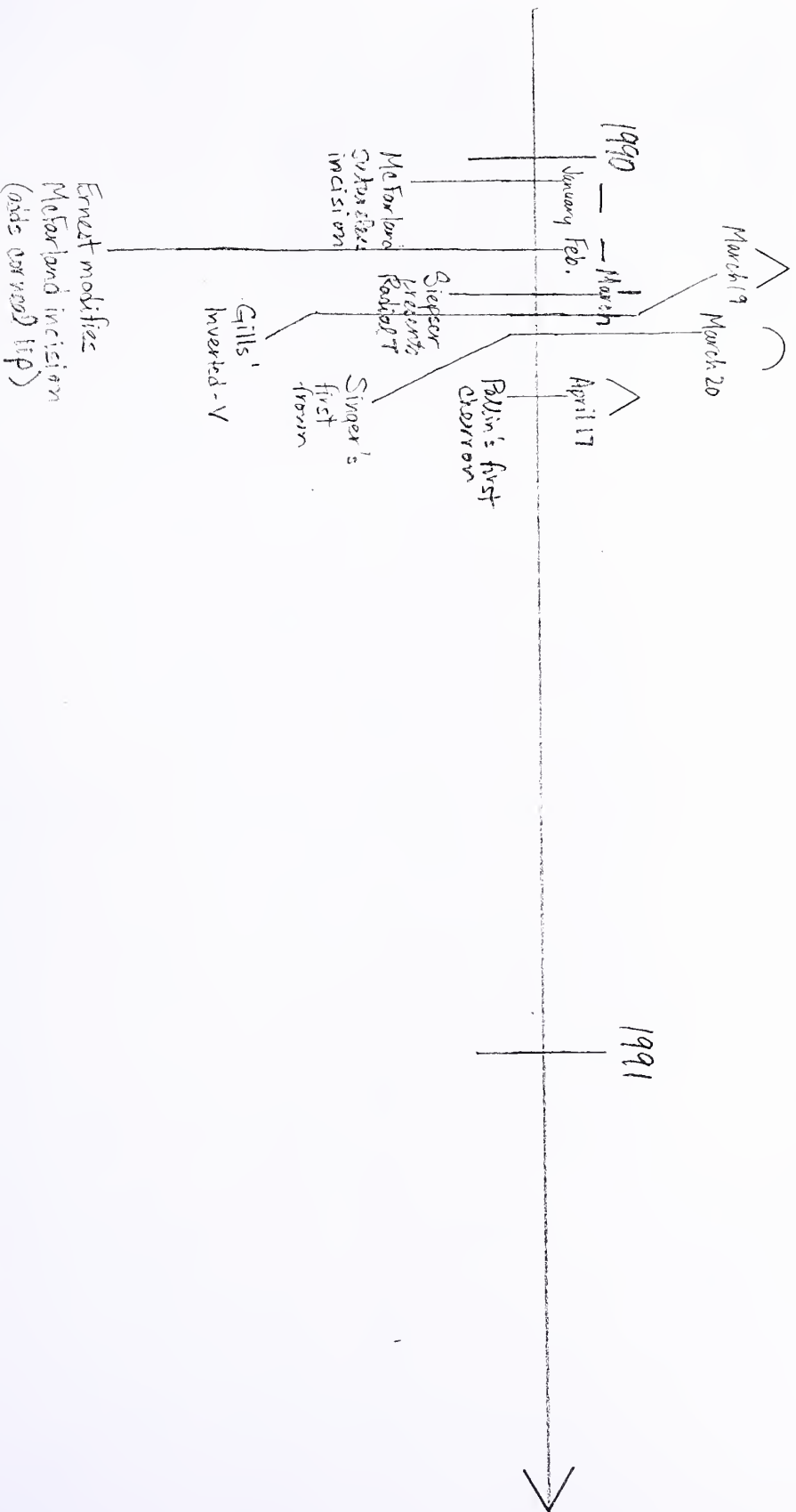
# TIMELINE 1B



\* Denotes incision distance (mm) posterior to limb



# TIMELINE 2A




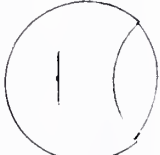
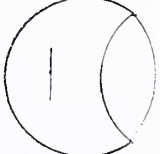
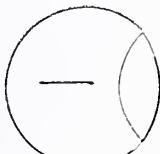




# FRAMEWORK FOR CORE ARGUMENTS A

	Defense's motion	Plaintiff's response	Defense's rebuttal
Argument venue			
Patentability			
<ul style="list-style-type: none"> <li>Patentable subject matter</li> <li>Utility</li> <li>Novelty (Anticipation)</li> <li>Nonobviousness</li> </ul>			
Primary considerations			
Secondary considerations			
<ul style="list-style-type: none"> <li>Disclosure/enablenent (Patent interpretation)</li> </ul>			
Non-patent-related venues:			
<ul style="list-style-type: none"> <li>Technical</li> <li>Credibility of witnesses and evidence</li> <li>Other</li> </ul>			
Safety of incision			
Judicial procedures			



## INCISION CONSTRUCTION DEBATE<sup>a</sup>

Surgeon:	Pallin	McFarland	Ernest	Stepper	Gills	Singer
Claimed development purpose (primary purpose):						
	Sutureless incision	Sutureless incision		Reduce/eliminate astigmatism		Reduce/eliminate astigmatism
Incision shape:	Chevron	Straight line	Straight line	Radial line	Inverted V	Frown
Distance from limbus <sup>b</sup> (mm):	1.5-3	3-4 <sup>c</sup>	3-4 (later 2mm)	1.5	1.5-3/4 initially (later 3-4)	2
Use of corneal lip (i.e. flap, seal, valve, component):	No	No	Yes	No	Yes	Yes (but not initially)
Claimed mechanism of self-sealing:	Length to width ratio of scleral tunnel > 1		Corneal lip		Corneal lip	Corneal lip
Other features:	Widening scleral tunnel	Relaxing cuts			Range of incision angle: 90 to 180 degrees	Initially used a suture
	Admits hard and soft lenses				Not clear if incision will admit hard lenses	

<sup>a</sup> Note: Blank cells indicate unknown or uncertain information.

<sup>b</sup> Distance of apex or midpoint of incision from limbus. The apex of Stepser's incision is the anterior endpoint.

<sup>c</sup> During the case, Ernest claimed that McFarland placed his incision 2-3 mm posterior to the limbus.





## CORE ARGUMENTS B

SECOND PHASE OF JUDICIAL PROCEEDINGS		Defense's Motion for Summary Judgment	Plaintiff's Opposition to Defense's Motion for Summary Judgment	Defense's rebuttal to plaintiff's opposition
Argument venue				
Patentability				
• Patentable subject matter				
• Utility				
• Novelty (Anticipation)		<ul style="list-style-type: none"><li>• Incisions of McFarland, Ernest, Gills, and Singer predated chevron incision</li></ul>	<ul style="list-style-type: none"><li>• Prior art must meet all features of the patented invention<ul style="list-style-type: none"><li>◆ McFarland: straight line, 3-4 mm distance, and relaxing cuts; lack of reduction to practice</li><li>◆ Ernest: same as McFarland with added corneal lip; lack of reduction to practice</li><li>◆ Gills: lack of conception and reduction to practice; abandoned his incision; did not measure; incision could not admit large lenses</li><li>◆ Singer: no reduction to practice; required a suture</li></ul></li></ul>	<ul style="list-style-type: none"><li>◆ McFarland: patent does not comment on relaxing cuts</li><li>◆ Gills: did not abandon – merely changed technique; practiced what the patent teaches about admitting large lenses</li><li>◆ Singer: suture use is taught by patent</li></ul>
• Nonobviousness				
Primary considerations		<ul style="list-style-type: none"><li>• Ernest says Pallin's invention is obvious in light of the work of Gills and Singer</li></ul>	<ul style="list-style-type: none"><li>• Sutureless surgery was not obvious to one of ordinary skill in the art</li></ul>	
Secondary considerations				
• Disclosure/enableness (Patent interpretation)		<ul style="list-style-type: none"><li>• Ernest says the phrase "substantially self-sealing" has no meaning</li></ul>	<ul style="list-style-type: none"><li>• Says term is defined properly</li></ul>	<ul style="list-style-type: none"><li>• Says Pallin uses circular reasoning to define phrase</li></ul>
Non-patent-related venues:				
• Technical		<ul style="list-style-type: none"><li>• Corneal lip, not geometric shape or location of incision, provides sealing</li></ul>	<ul style="list-style-type: none"><li>• Mechanism for sealing lies in the length to width ratio of the scleral</li></ul>	<ul style="list-style-type: none"><li>• Pallin's incision closure mechanism is not described in patent</li></ul>



## CORE ARGUMENTS B

SECOND PHASE OF JUDICIAL PROCEEDINGS	Defense's Motion for Summary Judgment	Plaintiff's Opposition to Defense's Motion for Summary Judgment	Defense's rebuttal to plaintiff's opposition
<ul style="list-style-type: none"> <li>• Credibility of witnesses and evidence</li> </ul>	<p>strength</p> <ul style="list-style-type: none"> <li>• Singer says the frown incision is stronger than the chevron, has less wound slide, and induces less astigmatism<sup>a</sup></li> <li>• Ernest says chevron and frown with the same internal construction behave substantially the same</li> </ul>	<p>tunnel, not in the corneal lip</p> <ul style="list-style-type: none"> <li>• Gills' 1994 testimony contradicts his 1990 book</li> <li>• Gills does not measure his incisions</li> <li>• Gills presents mismatched photographic evidence</li> </ul>	<ul style="list-style-type: none"> <li>• Measurements specified in patent do not always support tunnel length-width ratio <math>&gt; 1</math></li> <li>• Pallin has testified to the equivalence of the chevron and frown</li> </ul>
<ul style="list-style-type: none"> <li>• Other</li> </ul>			
<p>Safety of incision</p>	<ul style="list-style-type: none"> <li>• Ernest says incisions lacking a corneal lip (incisions of Pallin, Singer, McFarland, and Gills) are unsafe</li> </ul>		
<p>Judicial procedures</p>		<ul style="list-style-type: none"> <li>• Obviousness arguments not adequately developed as specified in <i>John Deere</i> case</li> </ul>	<ul style="list-style-type: none"> <li>• Alternative formats exist</li> </ul>

<sup>a</sup> Singer stated this in deposition in November 1993. His comment is not included in the main text of this paper.



# GILLS' ISSUE OF MEASUREMENT REFERENCE

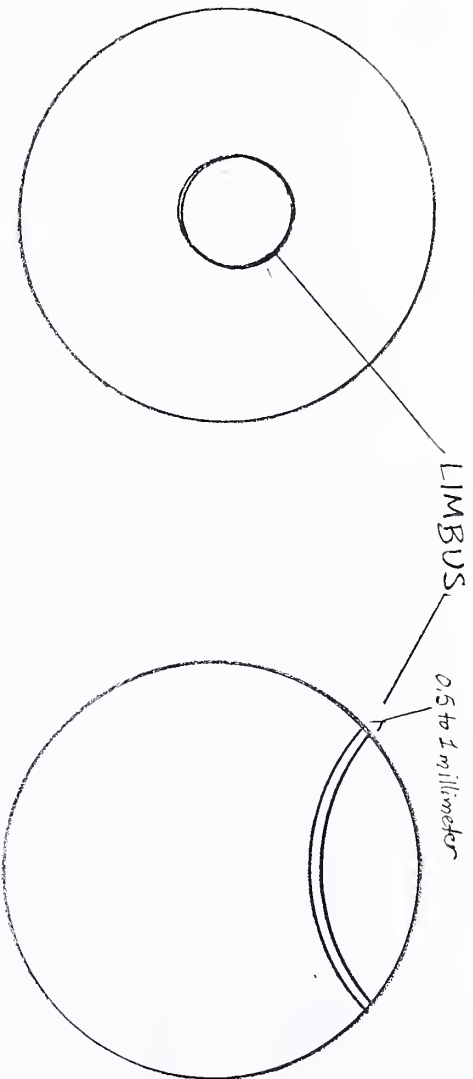
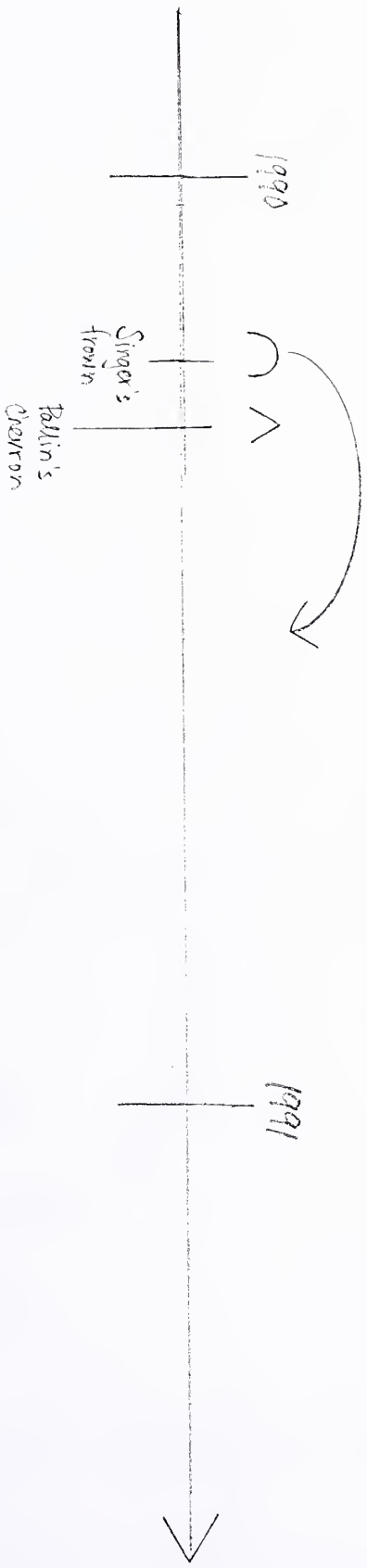


FIGURE 1 ("Second Phase of Judicial Proceedings")



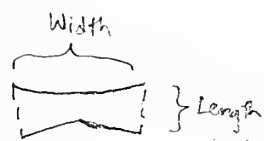
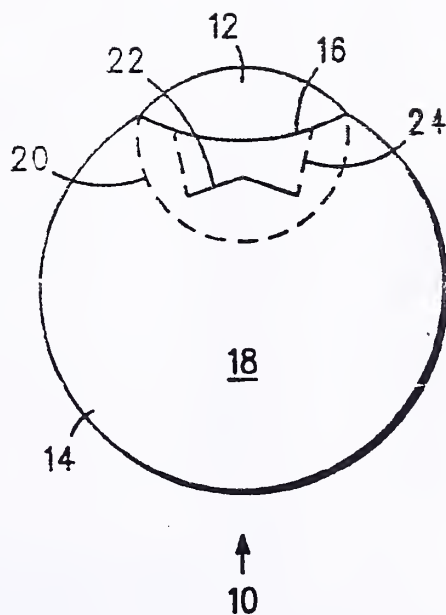
# Timeline 2B







TUNNEL LENGTH < WIDTH



Length < Width

FIGURE 2 ("Second Phase of Judicial Proceedings").



## CORE ARGUMENTS C

THIRD PHASE OF JUDICIAL PROCEEDINGS		Defense's second Motion for Summary Judgment	Plaintiff's opposition to summary judgment and Cross Request for Patent Not Invalid	Defense's rebuttal to plaintiff's opposition
Argument venue				
Patentability				
<ul style="list-style-type: none"> <li>Patentable subject matter</li> <li>Utility</li> </ul>				
<ul style="list-style-type: none"> <li>Novelty (Anticipation)</li> </ul>		<ul style="list-style-type: none"> <li>Fine says Pallin's patent covers even low-arc incisions facing the limbus</li> <li>Gills says he measured his incisions, which fell within range in Pallin's patent</li> <li>Singer omitted suture because he began to use corneal seal, not to effect self-sealing</li> </ul>	<ul style="list-style-type: none"> <li>Incisions of others did not achieve the advantages of Pallin's incision (e.g. preventing "oarlock" effect)               <ul style="list-style-type: none"> <li>Gills: no permanent idea of invention; "estimated, guessimated", failure to keep notes of procedures</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Gills used same incision distance and geometry as Pallin; did not abandon his work</li> <li>Singer used suture as specified in patent</li> </ul>
Nonobviousness				
Primary considerations		<ul style="list-style-type: none"> <li>Gills says Pallin's incision at 175 degrees is obvious</li> <li>Ernest says solving oarlock effect is obvious</li> <li>Hypothetical inventor in the field would have access to Gills' inverted V technique in April 1990</li> <li>Flurry of sutureless incision development activity in wake of Sieper's presentation</li> </ul>	<ul style="list-style-type: none"> <li>Sutureless surgery was not obvious to one of ordinary skill in the art</li> </ul>	<ul style="list-style-type: none"> <li>Every feature of Pallin's patent claims is represented in incisions of others (any number of prior inventions, each of which contains only one feature of a patented invention can render the invention obvious)</li> <li>Hypothetical inventor in April 1990 with access to all relevant prior art (e.g. inverted V) would find Pallin's technique obvious</li> <li>Solving the problem of "oarlock" is obvious to any ophthalmic surgeon</li> </ul>
Secondary considerations		<ul style="list-style-type: none"> <li>Sutureless method adopted in the field, but not Pallin's method</li> <li>Other surgeons solved long-felt need before Pallin did</li> </ul>	<ul style="list-style-type: none"> <li>Gills failed to invent and abandoned his incision</li> </ul>	<ul style="list-style-type: none"> <li>Flurry of sutureless incision development activity after Sieper's March 1990 presentation</li> </ul>



## CORE ARGUMENTS C

THIRD PHASE OF JUDICIAL PROCEEDINGS		Defense's second Motion for Summary Judgment	Plaintiff's opposition to summary judgment and Cross Request for Patent Not Invalid	Defense's rebuttal to plaintiff's opposition
• Disclosure/enablement (Patent interpretation)	<ul style="list-style-type: none"><li>• Cites <i>3M v. Research Medical</i> which stated that use of an invention in its intended manner (i.e. in an operating room) constitutes disclosure</li><li>• Gills disclosed invention in 30 lectures after March 1990</li><li>• Singer disclosed the frown incision in journals, video, and symposia</li><li>• Pallin's patent is internally inconsistent (i.e., use of suture for sutureless incision)</li></ul>	<ul style="list-style-type: none"><li>• If multiple interpretations of a patent exist, that which secures to the invention to the patentholder is adopted (Supreme Court precedent)</li><li>• Says term is defined properly</li></ul>	<ul style="list-style-type: none"><li>• Pallin has said that a suture may be required for larger incisions</li></ul>	
	<ul style="list-style-type: none"><li>• "Substantially self-sealing" has no meaning to one skilled in the art</li></ul>		<ul style="list-style-type: none"><li>• Pallin's claims of a watertight and sutureless incision renders the word "substantially" meaningless</li></ul>	
Non-patent-related venues:				
• Technical	<ul style="list-style-type: none"><li>• Pallin now using Singer's corneal tissue seal</li><li>• Pallin does not provide reference point on limbus</li></ul>			
• Credibility of witnesses and evidence	<ul style="list-style-type: none"><li>• Gills and his assistant report measuring incisions</li><li>• Pallin is only interested in money, engaged in inequitable conduct at PTO, and employs inconsistent patent strategy</li></ul>	<ul style="list-style-type: none"><li>• Pallin says he was not aware of Gills' work in April 1990 and believed the work of Siepser and McFarland had no bearing on his patent</li><li>• Gills: contradictory testimony; contradictions with staff testimony; erroneous notes and unauthenticated photo offered as evidence</li></ul>	<ul style="list-style-type: none"><li>• Gills' testimony is corroborated by staff, books, and patient records; has offered corrected notes; and photograph of Patient 208120 is authenticated</li><li>• Pallin failed to disclose prior art that may have been relevant to PTO examination</li></ul>	
• Other				
Safety of incision				



CORE ARGUMENTS C

THIRD PHASE OF JUDICIAL PROCEEDINGS	Defense's second Motion for Summary Judgment	Plaintiff's opposition to summary judgment and Cross Request for Patent Not Invalid	Defense's rebuttal to plaintiff's opposition
Judicial procedures		<ul style="list-style-type: none"><li>Gills has submitted new evidence (e.g., changed testimony, Ausmus declaration, photo of Patient 208120)</li></ul>	





# HOWARD FINE'S VIEW OF PATENT CLAIM 1 AND INCISION SHAPES

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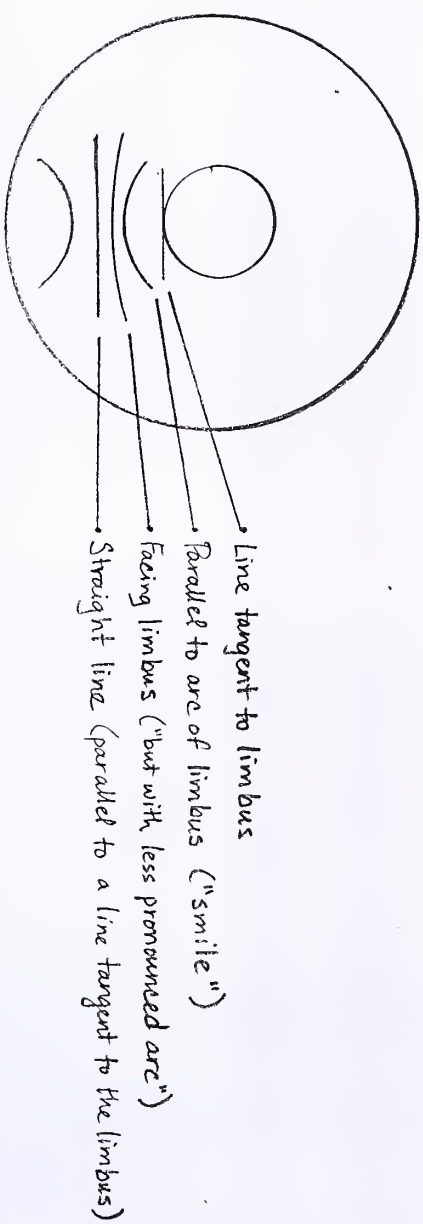


FIGURE 1 ("Third Phase of Judicial Proceedings")



## CHRONOLOGY

Listed below are key events in the controversy over *Pallin v. Singer*.

### 1980s

- Pallin begins quest to develop the chevron incision after hearing a statement by Dr. Jim Gills that it should be possible to create a watertight and sutureless incision for cataract surgery
- During the case, MacKool (defense witness) claims to have used scleral incision curving away from limbus in 1985-86
- MacKool claims to have stopped using a suture in the 1989-91 timeframe

### 1990

- January
  - February
  - March 4-7
  - March 1
  - March 19
  - March 20 and 27
  - April 17
  - June 28
  - August
  - November
- McFarland performs first straight-line sutureless incision
  - Ernest modifies McFarland's incision by adding a corneal lip
  - Siepser presents his radial transverse ("Radial T") incision at *The Symposium on Cataract, IOL and Refractive Surgery* in Los Angeles
  - Singer attends symposium
  - McFarland discloses his incision technique in *Ocular Surgery News*
  - Gills performs first inverted-V incision
  - Singer performs first frown incision
  - Pallin performs first chevron incision and submits article to the *Journal of Cataract and Refractive Surgery* the following day
  - Pallin files patent application for a "Self-sealing Episcleral Incision"
  - Singer publishes article on the frown incision in the same issue of *Ocular Surgery News* that printed an article on the chevron incision
  - Gills' book goes to press and is distributed later in the year
  - Pallin publishes Letter to Editor in *Journal of Cataract and Refractive Surgery*

### 1991

- February
  - October
  - October 16
- Singer begins to use a corneal lip
  - *Journal of Cataract and Refractive Surgery* prints Supplement issue entitled "Small Incision Surgery: Wound Construction & Closure," which contains technical articles by Pallin, Singer, and other participants in *Pallin v. Singer*
  - Pallin asks his attorney, Harry Wolin, to perform a patent search

### 1992

- January 14
- Patent # 5,080,111 is formally issued

### 1993

- July 6
  - September 3
  - October 14
  - November 5
- *Pallin v. Singer* begins
  - Pallin's attorneys file Complaint against Jack Singer and the Hitchcock Associates of Randolph for infringing and inducing others to infringe U.S. Patent #5,080,111
  - Attorneys for Singer and the Hitchcock Clinic respond to the Complaint
  - White offers Singer a license of \$2,500 -- \$10,000 per year which could be increased at Pallin's discretion
  - Singer deposed



## 1994

- January 7
  - Pallin deposed as a fact witness
- February 17
  - Harry Wolin, Pallin's patent attorney, deposed
  - Singer and Collins, CEO of the Hitchcock Clinic, send a letter to ophthalmologists around the country urging them to contribute to the Singer Defense Fund and to fight Pallin
- April 10
  - Their letter is printed in the April 1, 1994 issue of *Ocular Surgery News*
  - James Longacre attends the annual meeting of the American Society of Intraocular Surgeons
  - At the meeting, Singer solicits funds for his legal defense and discusses the alleged invalidity of Pallin's patent
  - Singer adapts his presentation ("The Free Exchange of Medical and Surgical Knowledge") to pamphlet and article form and continues to disseminate it through 1996
- April 19
  - Plaintiff offers one-time \$5,000 settlement
- April 20
  - In response to the defense's query as to what the plaintiff intends to do with his patent, Longacre replies that Pallin's intentions are his business and have no part in any settlement
- April 28
  - Plaintiff files motion to compel Singer to answer questions about the development of the frown, solicitation of legal defense funds, and his views on patent validity and infringement. The plaintiff also tried to compel the defense to identify its expert witnesses and limit its expert witnesses to one.
- May 12
  - Defense accuses Pallin of inequitable conduct at the PTO
  - Judge Billings denies plaintiff's motion to compel and allows defense to add a charge of inequitable conduct against Pallin
- June 13
  - Pallin deposed as expert witness
- Summer
  - AMA House of Delegates criticizes the patenting of medical methods
- July 26
  - Plaintiff unilaterally grants license on July 26
- July 29
  - Defense declares it will continue to pursue case until Pallin's patent is dedicated to the public
- October 3
  - Defense moves for summary judgment on the issue of patent invalidity
- December 5
  - Plaintiff files opposition to defense's motion for summary judgment

## 1995

- 1995
  - The PTO creates a new art unit for medical methods within the larger medical devices group, hires medical professionals, and reduces the workload of examiners reviewing medical method inventions
- January 4
  - Defense responds to plaintiff's opposition to summary judgment
- March 3
  - Representatives Ganske and Wyden introduce H.R. 1127 – "Medical Procedures Innovation and Affordability Act"
- May 1
  - Judge Billings denies summary judgment, citing "complex factual disputes" and failure of the defense to address secondary considerations of nonobviousness
- May
  - ASCRS and other medical organizations release white paper which calls for a legislative ban on patents for medical and surgical procedures
- June 17
  - Pallin debates health law professor George Annas on National Public Radio program "All Things Considered"
- June 18
  - AMA House of Delegates condemns the patenting of medical methods and advocates that the AMA work with Congress to legislatively prohibit it
- June 19
  - Pallin publishes short article titled "Patents spread new ideas" in *USA Today*
  - AMA Council on Ethical and Judicial Affairs releases its report on patenting medical procedures



- Summer
- September 8
- October 5
- October 18
- October 19
- November 15
- November 27
- AMA co-sponsors a medical procedure patent briefing for Congress, in which Singer participates as a panelist
- Judge Billings reassigns *Pallin v. Singer* to Judge William Sessions III
- Settlement conference is scheduled for November
- Senator Frist introduces S. 1334 – also titled “Medical Procedures Innovation and Affordability Act”
- House Subcommittee on Courts and Intellectual Property holds hearing to discuss H.R. 1127
- Pallin and Singer testify at the hearing
- Neuner informs Judge Sessions of the recent *Markman* ruling
- Judge Sessions holds status conference to determine if Markman hearing should be held

## 1996

- January 23
- February 13
- February 23
- February 27
- March 21
- March 25
- March 28
- April 23
- May 2
- May 24
- June
- July
- September 30
- Markman hearing rescheduled to March 26-28
- Defense files second motion for summary judgment
- Defense opposes plaintiff's request for 60-day extension to examine new evidence (Gills' revised testimony, declaration of William Ausmus, and photograph of Patient 208120)
- White informs Court that Pallin sustained an injury while horseback riding which might preclude his presence at the Markman hearing
- Plaintiff files opposition to defense's motion for summary judgment
- Plaintiff files summary judgment for Patent Not Invalid
- Plaintiff moves to exclude Ausmus Declaration and photograph of Patient 208120
- Defense opposes motion to exclude evidence
- Judge Sessions issues Consent Order which invalidates Claims 1, 7, 22, and 28 of Pallin's patent, enjoins Pallin from enforcing the remaining claims of his patent, and declares that the defendants did not infringe Pallin's patent
- *Pallin v. Singer* ends
- U.S. Supreme Court upholds *Markman* ruling
- U.S. Patent and Trademark Office holds hearing on patent protection for therapeutic and diagnostic methods
- ASCRS files complaints with the Federal Trade Commission, the Attorney General of Arizona, and the Arizona Board of Medical Examiners, alleging that Pallin has engaged in deceptive advertising
- AMA Board of Trustees and Pharmaceutical Research and Manufacturers of America Board of Directors meet to resolve differences over Ganske and Frist bills (H.R. 1127 and S. 1334)
- Representative Ganske attempts to amend the PTO appropriations bill to include a provision prohibiting medical method patents which does not prohibit new use patents
- Section 616 of Public Law 104-208, which bans the enforcement of medical method patents against health care providers, becomes law





## I. Introduction

At the core of the story of Dr. Samuel Pallin and the chevron incision is the question: Is it acceptable to obtain and enforce patents on medical methods? Those in favor of medical method patents believe that such patents spur invention, encourage disclosure of new knowledge, decrease health care costs, and accord with the U.S. patent system which has been successful in promoting technological and economic progress for over 200 years. Those opposed to medical method patents believe that such patents lower the quality of patient care, compromise physician autonomy and the doctor-patient relationship, hinder the dissemination of knowledge, and increase costs and litigation. The two viewpoints represent a conflict of two values – the legal right to patent medical inventions and the moral right to use any medical knowledge.<sup>1</sup>

This paper will focus on the patent infringement case of Dr. Samuel Pallin versus Dr. Jack Singer. Pallin, an Arizona ophthalmologist, claims to have invented his “chevron” sutureless incision technique in April 1990. It provided many advantages over traditional methods, among them self-sealing (elimination of the need for a suture), ability to use soft and hard lens implants, and easier access to the anterior chamber of the eye for instrument manipulation.<sup>2</sup> A medical journal refused to publish Pallin’s report of his technique. Consequently, Pallin applied for a U.S. patent on his technique. Furthermore, Pallin charged royalties for the use of his patented technique – initially at \$2,500 to \$10,000 per year. Singer, a Vermont ophthalmologist, employed, taught, and wrote about his “frown” sutureless incision technique, which was similar if not identical to Pallin’s invention. But Singer refused to pay royalties. In 1993, Pallin sued Singer and the clinic where Singer worked for patent infringement. It is believed to be the first time one physician has sued another physician for infringement of a medical method patent.<sup>3</sup> The American

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<sup>1</sup> It is understood one might believe that a moral right to own private property is inherent in the legal right to patent.

<sup>2</sup> Pallin also claimed that his incision technique possessed lower probability of corneal fold formation which can hinder visualization during surgery. Pallin, S. “Chevron sutureless closure: A preliminary report,” *Journal of Cataract and Refractive Surgery*, 17: 706-9. Supplement 1991, p. 707.

<sup>3</sup> No commentator has stated the contrary. William Noonan, an ophthalmologist and patent attorney, has written a number of articles on patenting in medicine and biotechnology. In a Congressional hearing, he stated, “To my knowledge, the Pallin-Singer litigation is the first procedure patent lawsuit that has been pursued in modern legal history.” See “Hearing before the Subcommittee on Courts and Intellectual Property of the Committee on the Judiciary / House of Representatives / One Hundred Fourth Congress,



Medical Association (AMA) and other medical societies vigorously denounced Pallin's actions and more broadly denounced the patenting of any medical procedure. Members of Congress subsequently introduced legislation banning patents on medical procedures. The only existing ban on patenting at that time was that for inventions which jeopardize national security such as atomic weapons. Legislative activity culminated in September 1996 in the enactment of Section 616 of Public Law 104-208 which prohibited the enforcement of medical procedure patents against health care providers.

Studying this case and the controversy it created enlightens us about the execution of a patent infringement case, the behavior of the medical profession, and the values of society. It is relevant in understanding the recent tendency to enforce medical method patents. Three medical method patents have assumed high profiles in recent years. Dr. John Stephens has demanded royalties from physicians for using his patented technique of determining the sex of a fetus by identifying external genitalia on radiologic images.<sup>4</sup> Men's Health Resources, Inc. (MHR), which owns a patented technique for treating impotence with penile drug injections, charged 500 urologists with a license fee of \$350 per year.<sup>5</sup> The technique was invented in 1978 by Dr. Alvaro Latorre, whose estate sold the patent to MHR. Dr. Mark Bogart has aggressively enforced his patented statistical algorithm that relates the level of a hormone detected in a pregnant woman's blood to the occurrence of Down's Syndrome in her child.<sup>6</sup> Bogart has already received millions of dollars from laboratories that use his patented method.

This thesis project aims to tell the story of the chevron incision and to comment on the effects of Pallin's lawsuit on his patent and on the medical profession, to understand the basis for

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First Session on H.R. 1127: Medical Procedures Innovation and Affordability Act and H.R. 2419: Inventor Protection Act of 1995," October 19, 1995. U.S. Government Printing Office: Washington, p. 72. Hereafter referred to as "Hearing."

<sup>4</sup> Neergaard, L. "Move to Patent Surgical Procedures Sparks Fight; Royalties: Doctors Say Controlling the Way They Practice Medicine in Such a Way is Unethical and Drives Up Health Care Costs. They've Persuaded Congress to Consider Outlawing the Practice," *Los Angeles Times*, April 2, 1995, p. 14A. Also see October 3, 1995 Letter from Dr. Stephens to Rep. Carlos Moorehead in Hearing, p. 121. Stephens writes: "I should also wish to have it noted for the record that I personally have not pursued enforcement of the patent." Perhaps, an institutional entity like his sonology laboratory (Koala Labs, which he owns) has enforced the patent.

<sup>5</sup> Lowes, R. "Are you stealing from other doctors? Medical procedure and method patents," *73 Medical Economics*, March 11, 1996, p. 195.

<sup>6</sup> The hormone is human chorionic gonadotropin (hCG), which is the basis for many home pregnancy tests. See Borzo, G. "Lawsuit heats up over patent on common prenatal test," *American Medical News*, January 12, 1998, pp.1, 27, 30.



banning medical procedure patents (or their enforcement), and to understand why participants in this controversy behaved as they did. Of particular interest are why Pallin chose to charge royalties on the use of his technique when it would appear to run counter to the ethos of the medical profession, why Pallin chose to sue Singer, why the AMA and other professional organizations opposed the patenting of medical procedures, and why Congress was motivated to legislate on this issue.

Three specific hypotheses will be examined: Pallin's patent was invalid because it was issued for an invention that was obvious in the context of patentability<sup>7</sup>; the AMA is inconsistent in its views on the patenting of medical inventions (the AMA supports the patenting of medical products but opposes the patenting of medical methods); passage of Section 616 of Public Law 104-208 represents the efforts of professional interests to create special status under intellectual property law for a particular kind of inventive activity, a special status that is unnecessary in light of the notion that administrative changes at the U.S. Patent and Trademark Office can accomplish their objectives.

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<sup>7</sup> The author hypothesized this after perusing a 1991 *Journal of Cataract and Refractive Surgery* Supplement issue devoted to small incision cataract surgery. This issue contained 17 articles, 10 of which discussed self-sealing or sutureless incisions. Singer, Pallin, and other ophthalmologists who had prominent positions in the case published in this issue. The Supplement issue was published one to two years after Pallin claims to have invented his incision. It appeared that Pallin was not the only ophthalmologist developing sutureless incisions in the 1990-91 timeframe. Thus, his chevron incision method may not have been sufficiently original (nonobvious) to deserve a patent.



## II. The infringement

Civil Action No. 5:93-cv-202 (filed July 6, 1993)<sup>1</sup> read:

In the United States District Court for the District of Vermont /  
 Samuel L. Pallin M.D.  
 Plaintiff  
 vs.  
 Jack A. Singer M.D. and  
 Hitchcock Associates of Randolph  
 Defendants

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### Lodging a Complaint

In July 1993, almost a year and a half after his patent was formally issued (U.S. Patent #5,080,111, "Method of Making Self-Sealing Episcleral Incision," issued January 4, 1992), Dr. Samuel Pallin filed a Complaint in the U.S. District Court of Vermont alleging that Dr. Jack Singer willfully and deliberately infringed his patent and that Singer and Hitchcock Associates of Randolph had carried out hundreds of cataract operations using the self-sealing incision covered by his patent even though they knew of his patent.<sup>2</sup> Pallin said that Singer had also induced others to infringe by teaching the incision technique.<sup>3</sup> In a letter predating the Complaint, one of Pallin's attorneys, John White, offered Singer the opportunity to purchase a license "for payment of a reasonable royalty" and also inquired about the past and future volume of Singer's surgeries which use the incision at issue.<sup>4</sup> The letter concluded with the following:

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<sup>1</sup> The plaintiff's attorneys were John M. White and Mikolean Y. Morgan of Longacre & White in Arlington, Virginia. James Longacre, of the same firm, also participated. The defendants' attorneys were Peter J. Manus and George W. Neuner of Dike, Bronstein, Roberts & Cushman in Boston, Massachusetts. The defense was later turned over to Robert Portman and Kit Pierson, attorneys from Jenner & Block in Washington, DC.

<sup>2</sup> Complaint (filed 7/6/93) in court documents for *Pallin vs. Singer*, No. 5:93-CV-202 (D. Vt. filed July 6, 1993). Court documents stored in National Archives and Records Administration facility (for Northeast region) in Waltham, MA.

<sup>3</sup> The Complaint cites as evidence an article on the frown incision written by Singer in the 1991 Supplement to the *Journal of Cataract and Refractive Surgery*.

<sup>4</sup> June 4, 1993 Letter from John White to Jack Singer in Exhibit B of Complaint. White states that a license would require Singer to reference the patent and to state the necessity of a license in any promotion he made of the technique.





“The purpose of this letter is not to threaten, but rather to propose a businesslike solution. At the same time we must make clear that if you do not respond, or are unwilling to license under the patent, we will have no choice but to bring suit.”

Pallin sought to enjoin Singer and Hitchcock from inducing others to infringe and from using surgical methods which infringe his patent. Pallin’s attorneys requested a jury trial to assess and award damages and legal costs to Pallin.

*Pallin vs. Singer and the Hitchcock Associates of Randolph* (hereafter referred to as *Pallin v. Singer*) takes what is probably a classic beginning for an infringement case, in which one side alleges infringement, while the other side denies infringement and alleges that the patent is invalid. Alleging patent invalidity (akin to a counterlawsuit) creates an extra burden for the plaintiff who must now prove infringement while vigorously defending the patent. Thus, the plaintiff risks losing not only an infringement suit but also losing his patent monopoly as well. At the outset, the arguments were simple, but as the case moved forward, the core issue of patent infringement was deflected in favor of issues of patent application procedure, the inner workings of the invention, and witness credibility. The arguments assumed complexity and breadth, and the conception of Pallin’s invention changed over time.

On September 3, 1993, the defendants answered the plaintiff’s Complaint by denying patent infringement and by denying that Pallin’s invention is based on his fundamental discovery and invention. The defendants believed Pallin’s patent was invalid and therefore improperly issued by the U.S. Patent and Trademark Office. In their view, Pallin’s work was not new, and it was obvious to the ordinary ophthalmic surgeon. Thus, it did not meet the statutory requirements of patentability. The defendants also alleged that Pallin failed to specify the subject matter of his invention (e.g. process, machine, manufacture) and also failed to produce a written description of the invention that would enable skilled practitioners to use it, thus not meeting the legal requirements of patentability.

The plaintiff appeared eager to litigate this case. The defendants’ counsel, George Neuner and Peter Manus, noted that they had replied to the plaintiff’s license offer but that the plaintiff had already



commenced litigation.<sup>5</sup> Possible reasons may have included a desire for rapid resolution, a speedy offense which would prevent the defendants from mounting a vigorous defense, or a precedent of swift and vigorous attacks on infringers in hopes of deterring other would-be infringers. However, the plaintiff's apparent unwillingness to discuss a licensing arrangement while commencing litigation and his insistence on a jury trial suggests that the plaintiff sought a judicial stamp of approval for his patent. This would make it easier to enforce the patent and to charge royalties in the future. This view is supported by White's initial letter to Singer in which White requests the number of operations in which Singer has employed the sutureless incision technique and the number of future operations which will use the technique. While this information could inform the plaintiff's calculation of a "reasonable royalty" for Singer, it could also be utilized in sizing the market for Pallin's patent, which would be a natural first step in a campaign to create a "cash cow" in the form of a steady stream of royalty revenues.

In October, Pallin's attorney offered Singer a \$2,500 -- \$10,000 per year license which could be increased at Dr. Pallin's discretion. The plaintiff did not expect to recoup court costs in the case against Singer but expected to recoup them with future licenses.<sup>6</sup> The plaintiff stated, "The sooner we resolve matters with Dr. Singer the sooner we can move on to others." But no settlement was reached, and the judicial discovery process forged ahead.<sup>7</sup>

### Reaching Out to Ophthalmologists

On February 17, 1994, Singer and John Collins, CEO of the Hitchcock Clinic, under which Singer practiced, began a national campaign to support Singer's effort against Pallin. They sent a letter to ophthalmologists around the country, which was eventually published in the April 1, 1994 issue of *Ocular Surgery News*. It outlined their views on patenting medical methods:

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<sup>5</sup> Only 14-15 business days in the schedules of a busy ophthalmologist and his attorneys had elapsed between license offer and reply. The defendants replied on June 24, 1993, the very date of a follow-up letter from the plaintiff.

<sup>6</sup> Letter of 10/21/93. Both 10/14/93 and 10/21/93 letters mentioned in 2/17/94 Letter from Singer and Collins to ophthalmologists.

<sup>7</sup> Discovery is the process of collecting and synthesizing information relevant to the case (e.g. deposing witnesses). Deposition is the process of taking statements from or interviewing a witness under oath. Singer was deposed in November 1993, and Pallin and his patent attorney, Harry Wolin, were deposed in January 1994.



“We see no merit in the specific allegations, nor do we agree with the underlying premises of Dr. Pallin’s suit, i.e., that surgeons can or should patent the shape of incisions, or that giving reports on your own surgical experiences at professional meetings can constitute inducement of infringement. We believe that such patenting and such interpretation of what constitutes infringement is inconsistent with the applicable code of professional conduct and the advancement of medical science through the free and open exchange of ideas.”<sup>8</sup>

The letter took on a chilling tone in its efforts to paint a picture of a crisis facing the ophthalmologic community. Singer and Collins said that Pallin’s attorneys had “made it clear that [Pallin] intends to demand licenses from all surgeons, clinics, hospitals and other entities that use any incision located from 1.5 to 3 mm posterior to the limbus and diverging from the limbus.”<sup>9</sup> Furthermore, they mentioned a July 1993 telephone conversation between legal counsel in which Singer is described by Pallin’s attorneys as the first target “in what we expect is a rather long line of people.” Singer and Collins also warned of an anonymous survey that has been sent from “L&W” to ophthalmologists. They believed answers to the survey would help Pallin and his attorneys decide which ophthalmologists to target in the future. Singer and Collins believed “L&W” stood for Longacre and White, Pallin’s attorneys.

Reporting that \$110,000 had been expended to date in Singer’s lawsuit, Singer and Collins solicited contributions for the Singer Defense Fund saying that Singer’s defense would benefit the profession. Surplus funds would support efforts to change patent law to prohibit patents on “pure methods” of medical and surgical treatment. Finally, Singer and Collins solicited intangible contributions to bolster Singer’s legal position:

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<sup>8</sup> 2/17/94 Letter from Singer and Collins to ophthalmologists.



“Of course, we also welcome other assistance, for example, any information you may have regarding scleral incisions used in eye surgery prior to June 1990, whether in the nature of the operations you have conducted or observed, articles or books you have read, or conversations with others regarding their work.”

Pallin filed his patent application in 1990. If Singer and Collins could show that Pallin was not the first to invent his incision, they could invalidate his patent.

Two months later, White’s law partner, James Longacre, attended the annual meeting of the American Society of Intraocular Surgeons where he heard Singer deliver a talk entitled “Free Exchange of Medical and Surgical Knowledge” in which Singer solicited funds for his legal defense and discussed the alleged invalidity of the Pallin patent. On April 19, in a letter offering settlement terms, Longacre wrote to Neuner:

“It became apparent to me listening to Dr. Singer at length at the Cataract Society meeting just concluded that Dr. Singer’s fundamental objection is not to the Pallin patent alone, but to the present availability of method patents on surgical techniques to anyone.”<sup>10</sup>

Longacre’s letter proposed a one-time \$5,000 settlement, which Longacre viewed as an appropriate fee considering Singer’s efforts in promoting the incision technique.<sup>11</sup>

#### Entrenching for legal battle

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<sup>9</sup> The limbus is the transition zone between the clear portion (cornea) and white portion (sclera) of the eye. The limbus serves as an anatomical landmark in cataract surgery. Pallin’s patented invention covers a particular location and configuration (shape) for a sutureless incision.

<sup>10</sup> 4/26/94 affidavit of James Longacre in Motion to Compel (filed 4/28/94).

<sup>11</sup> The offer would remain effective for only three days (until 5pm on April 22, 1994).





Longacre appeared eager to settle, probably to avoid a protracted legal battle in which it appeared that Singer could have drawn from coffers full of funds. By settling, Longacre could quickly obtain a limited stamp of approval on the patent and move on to the next case. In an April 20 letter to Neuner, Longacre reiterated his contention that the defense had not shown any proof of invalidity to overcome the court's presumption of validity of the Pallin patent. He then proceeded to assert that the marketplace success of Pallin's incision demonstrated that it was not an obvious invention. He cited the fact that Pallin was originally refused publication and the statistic that 34% of surgeons now used the Pallin incision. In his view, "Initial skepticism by the art [(the ophthalmology profession)], and commercial success following skepticism are strong evidence that the invention is unobvious." Longacre's final plea consisted of an appeal to the moral sensibilities of the defense couched in a counselor-to-counselor tone:

"Dr. Pallin has stated on a number of occasions that he would never seek an injunction or an unreasonable royalty from a surgeon or anyone else so you and Dr. Singer may be assured that no one will be stopped from using this incision in the future. At the most they will be asked to pay a small royalty. . . . George, you and your client have spent an enormous amount of effort, time, and money trying to invalidate this patent. If you haven't done it by now, why do you think you will ever do so?"<sup>12</sup>

If the defense pondered settling for even just a moment, that moment was lost with Longacre's reply to Neuner's query as to what the plaintiff intended to do with his patent in the future. Longacre's answer swayed the defense to assume a no-compromise position:

"What we do with the patent in the future with respect to others who are not defendants in this law suit is our business and has no proper part in

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<sup>12</sup> 4/20/94 Letter from Longacre to Neuner in Motion to Compel (Exhibit N).



any settlement. However, there is no reason to disclaim the patent and we will not do so. The patent is valid and infringed and you have provided no evidence to the contrary.”<sup>13</sup>

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<sup>13</sup> 4/20/94 Letter from Longacre to Neuner in Motion to Compel (Exhibit N).



### III. Who is Pallin?

#### Biographical Sketch<sup>1</sup>

The son of a physician, Samuel Pallin always knew he was going to be a physician. His family told him that since the age of three or four, he expressed a desire to practice medicine. After finishing premedical studies at Hofstra University in 1963, Pallin attended the State University of New York Health Science Center (also known as Downstate Medical School) in Brooklyn, and earned an MD in 1968. While Pallin was in medical school, he became very excited about cardiac surgery as Dr. Christian Bernard had performed the first heart transplant. Pallin completed a surgical rotating internship at Long Island Jewish Medical Center in 1969. He had planned to complete a surgery residency and cardiovascular fellowship, but as a member of the Berry Plan during the Vietnam conflict, he obtained a student deferment and entered military service. After internship, he spent a few months doing cardiovascular research and then entered the Air Force. As a flight surgeon, Pallin had substantial exposure to ophthalmology. After some thinking, he concluded that he did not want to pursue cardiovascular surgery because “you seem to lose as many as you win.” He found ophthalmology attractive:

“ophthalmology was more meticulous and more to my liking, and also more closely allied to physics. Everything has an explanation in ophthalmology.”<sup>2</sup>

Pallin trained at the Brooklyn Eye and Ear Hospital from 1972 to 1975. He preferred performing ophthalmic surgery over fitting eyeglasses; thus, he planned to practice in an area with a large senior population. He considered Florida briefly but then chose to start private practice in Sun City, Arizona in 1975. Pallin is currently the CEO of the Lear Eye Clinic which has two sites in the Phoenix area. The

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<sup>1</sup> Transcript of Interview with Dr. Samuel Pallin at his home in Scottsdale, Arizona (Interview conducted by B. Rengarajan), April 24, 1998. Hereafter referred to as “Pallin interview”; Curriculum Vitae of Samuel Lear Pallin, M.D., F.A.C.S.

<sup>2</sup> Pallin interview (4/24/98), p. 1.



Lear Eye Clinic specializes in adult ophthalmology with an emphasis on cataract surgery, although clinic staff also provide refractive surgery, occasional corneal transplants, arcade work, and glaucoma treatment. Pallin estimates that he performs almost a thousand cataract operations in a good year.<sup>3</sup>

A board-certified surgeon with membership in many professional societies and staff privileges at numerous hospitals, Pallin has always engaged in academic and inventive activity. He has trained in the use of radial keratotomy, YAG laser, and Eximer laser and has taught courses on radial keratotomy, phacoemulsification, and sutureless cataract surgery. He has also delivered numerous presentations and papers and has published in the ophthalmology literature. His work over the last twenty years has included comparing phacoemulsification and extracapsular cataract extraction, studying surgical techniques, reporting interesting cases, devising a manual aspiration tool, and developing a sutureless incision.<sup>4</sup> In his view, inventing is “what makes practice interesting, to be doing new things all the time.”<sup>5</sup>

### Beliefs, Values, and Perceptions in Medicine

In Dr. Pallin’s view, the isolated brotherhood that medicine used to be has inevitably progressed to become an industry because health care has come to constitute a large part of the gross national product and has become dependent on technology:

“The doctor of the 1950s got in his little Buick -- well it wasn’t little, it was a big Buick -- which was probably two or three years old and made a house call with his little black bag. And he felt capable of walking into that house, taking the temperature, smelling the breath and

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<sup>3</sup> Pallin interview, p. 2.

<sup>4</sup> See “Comparison of induced astigmatism with phacoemulsification and extracapsular cataract extraction,” *Journal of Cataract and Refractive Surgery*, 13: 274-8. May 1987; S. Pallin and G. Walman, “Posterior chamber lens insertion using Healon to position capsular flaps,” *American Intra-ocular Implant Society Journal*, 7: 270-1. Summer 1981; S. Pallin and G. Walman, “Two-looped anterior chamber lenses in complicated extracapsular cases,” 9: 33-5. Winter 1983; S. Pallin and G. Walman, “Vitreous management during secondary implantation,” *American Intra-ocular Implant Society Journal*, 7: 271. Summer 1981; “Trauma and lens implantation,” (Letter to the editor) *American Intra-ocular Implant Society Journal*, 6:272-4. July 1980; “Spring-assisted manual aspiration”; “Chevron incision for cataract surgery,” (Letter to the editor) *Journal of Cataract and Refractive Surgery*, 16: 779-81. November 1990; “Chevron sutureless closure: A preliminary report,” *Journal of Cataract and Refractive Surgery*, 17: 706-9.





the urine, and making a diagnosis. He was offering that patient the best medicine had to offer in that age, that time. And it was legitimately the best. Can you imagine nowadays getting a call from a patient who says “I’m very sick, and you have to come to the house,” and having a little black bag with a reflex hammer, a stethoscope, a blood pressure cuff -- what else? You didn’t have dipsticks for the urine. We’re so dependent on technology to make the most basic diagnosis, the most rudimentary assessment of the patient, that we need the help of industry. We’re interlocked and intertwined. And the relationship is inescapable. And industry is so dependent upon intellectual property protection for its profit picture. So I don’t think it’s possible for physicians to be segregated and insulated from that environment anymore.”<sup>6</sup>

Pallin believes the industrialization of medicine in which a given industrial segment pairs with the appropriate medical specialty has led to a situation in which physicians fall prey to conflict-of-interest, especially in ophthalmology. A physician might be directly conflicted by earning consulting fees from manufacturers. He might own stock portfolios in companies that produce lenses. Or he might be “egotistically enlarged” by involving himself in clinical research or consulting for a company whose product he finds interesting. He is called upon to present his work at meetings and to publish his work. He gets a feather in his cap, “and it becomes very hard for him to see the dark side of that project.”<sup>7</sup>

As an example of this type of conflict-of-interest in which a physician has intimate dealings with a manufacturer of ophthalmic devices and equipment, which accrue to his reputation, Pallin offers the strong sentiment expressed by many ophthalmologists that foldable lens implants were superior to rigid lens implants. Pallin states that he has not seen any peer-reviewed literature that substantiates this view. Pallin

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<sup>5</sup> Pallin interview, p. 1.

<sup>6</sup> Pallin interview, p. 14.

<sup>7</sup> Pallin interview, p. 5.



recalls receiving a prospectus in the mail in the early 1980s which offered him the opportunity to purchase stock in a new company that was developing folding lens implants. Pallin declined to invest, but many of his colleagues did purchase shares. Pallin sees these investments as conflicts-of-interest, albeit “not in the strict sense of medical ethics.”<sup>8</sup> He illustrates with the following analogy:

“The fact that you own ten shares of General Motors doesn’t mean that if you’re an engineer [and] you do a research project comparing Ford, General Motors, and Chrysler --. It doesn’t mean that you will favor GM, but you might, and especially if you own a lot of stock or if you owned enough stock so that to you it was a large part of your portfolio.”<sup>9</sup>

Conflicts-of-interest may have thwarted Pallin’s efforts to publish his sutureless incision work. Pallin had originally reported his chevron incision in a submission to the journal of the *Journal of Cataract and Refractive Surgery*. To his dismay, the article was rejected. He believes elitism and non-inclusive politics contributed to the rejection, but he says there was an undercurrent supporting the soft lens market which ran counter to the nature of his invention:

“There was a lot of industry interest in selling soft implants. I don’t think anybody who was excited about soft implants and small incisions was very happy with the idea that an incision could be developed that every ophthalmologist could easily learn and any size or shape of lens implant would be admitted by that incision, making it harder to sell soft implants to the ophthalmic surgical community.”<sup>10</sup>

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<sup>8</sup> Pallin interview, p. 5.

<sup>9</sup> Pallin interview, p. 5.

<sup>10</sup> Pallin interview, p. 4.



Pallin notes that many technology-oriented companies in ophthalmology relied almost entirely on the investment of ophthalmologists, and many ophthalmologists made large investments in companies whose commercial life lie in developing folding lens implants. Pallin believes these phenomena occur in other medical specialties but believes they are rampant in ophthalmology. According to Pallin, “It’s hard to read an article where you don’t suspect there is bias.”<sup>11</sup>

Pallin believes ethics have become unclear in medicine. He points out that in the 1950s, doctors received fees directly from patients but now receive fees from third-party insurers. Thus, it is difficult to practice “the old ethics” in which the relationship is between the doctor and the patient. It has become confusing where a doctor obtains his rewards. Nevertheless, Pallin says he knows what his ethics are:

“I have to go back to basics to be sure what my ethics are. The first principle is: do the right thing for the patient. That may be the only principle. But there used to be a second principle, and that is, in addition to doing the right thing for the patient: be sensitive to do the right thing for your colleagues. Now the second principle is an elegant principle. It’s a feel-good principle. I’m not sure it’s valid though. The only really valid ethical principle in medicine is: do the right thing for the patient. I don’t truly believe there is any another.”<sup>12</sup>

Pallin believes the ethical issues of today are different from those of the 1940s and 50s when his father served as chairman of the ethics committee of the Kings County Medical Society.<sup>13</sup> Pallin views the problems of the 40s and 50s, such as selling snake oil and fee-splitting between surgeons and general practitioners, as “real ethical transgressions.” However, the discussion of ethics he has observed in the 70s, 80s, and 90s has related to economics and competitive issues between physicians rather than to issues of the mistreatment of patients. Pallin is dismayed by the transition:

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<sup>11</sup> Pallin interview, p. 6.

<sup>12</sup> Pallin interview, p. 12.



“It was entirely appropriate to prevent doctors from selling snake oil and it was more appropriate to prevent doctors from splitting fees and operating on patients that didn’t need surgery. But to have doctors quibbling over whether or not one procedure belongs to one doctor or to another, I think, is just outrageous.”<sup>14</sup>

Pallin was referring to turf battles between medical specialties, but his phrasing is ironic. Only a few years before this author’s interview of him, Pallin was effectively engaged as a principal in a debate “over whether or not one procedure belongs to one doctor or to another,” or to all doctors.

Pallin was particularly troubled by changes in ethical standards in the early 1970s when he was an ophthalmology resident. He was alarmed by the “new tendency to profit from teaching in medicine.” According to Pallin, when ophthalmologists in earlier times enrolled in skills transfer courses, they typically paid low fees which would cover expenses. However, in the early 1970s, Charles Kelman, the inventor of phacoemulsification,<sup>15</sup> began teaching weekend courses for which he charged a thousand dollars. Kelman “had a very close relationship with the manufacturer of the equipment such that if a hospital or a doctor bought ophthalmology equipment, no one was permitted to touch that equipment or utilize that equipment who hadn’t taken Charlie’s course. If you did, the manufacturer voided the warranty. It was a nice tight-knit circle.”<sup>16</sup> Pallin says that skills transfer courses can now cost up to seven thousand dollars and that some physicians make a living strictly from teaching courses, earning up to a million dollars per year in one case.

Pallin says he was disgusted by the profit motive in medical teaching and saw it as a violation of the Hippocratic Oath which teaches physicians to educate junior colleagues without compensation. Pallin

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<sup>13</sup> Pallin says his father had served as the President of the Kings County Medical Society and President of the American Society of Anesthesiology.

<sup>14</sup> Pallin interview, p. 9.

<sup>15</sup> Phacoemulsification is a widely used technique of dissolving a cataract with an ultrasound probe and then aspirating the dissolved tissue.

<sup>16</sup> Pallin interview, p. 9.





concedes that the Hippocratic Oath is antiquated and many physicians believe the Oath no longer applies. However, Pallin believes that ethics are axiomatic:

“I think ethics should be regarded as axiomatic principles that are very simple like the basic rules of physics. They don’t change with the times. They’re not complicated. They don’t need to be amended. . . .I think it would be nice if teaching in medicine were still that way, but it’s not. It’s just a fact of life. I also think it was nice to extrapolate that doctors should not profit from intellectual property. They’re meant to share intellectual property.”<sup>17</sup>

Pallin says he concurs with the AMA of the 1950s which deemed medical patenting unethical. In his mind, this view of patenting prevents certain conflicts-of-interest. But he finds perplexing the present position of the AMA which allows patents on medical products but not on medical methods. Pallin believes this can lead to an inequity such as that found in federal taxation in which each state contributes a certain amount of money to the federal government and some of the states do not get back what they put in:

“I think unfortunately if you start to say physicians can claim their rewards in a certain way but not in another way, you start to get into that sort of thing. We all put the same amount into medicine. We spend our time, our lives, our intellectual curiosity, our emotional energy in medicine, largely for our patients, but a lot of it is good for our egos too. And then we turn around and collect fees, articles, awards, whatever it is we get back. I think what we’re getting into here when we’re talking about methods and patents and licensing fees -- we’re getting into the area of how much does Arizona get back from

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<sup>17</sup> Pallin interview, p. 10.



the government. How much does one doctor have a right to get back from his pursuits?"<sup>18</sup>

Asked if he would support fellow physicians who wanted to license their method patents and collect royalties, Pallin replied:

"I think what's good for the goose is good for the gander. If people are making fortunes from devices, I think it's totally justifiable that other doctors should be able to charge for methods. I think it's a much more pure form of medical intellectual property. So yes, I guess I would support it."<sup>19</sup>

Thus, although Pallin believes a world where physicians do not patent their medical inventions is ideal, he was willing to change his tune to adapt to a legal environment that allowed patenting of medical inventions by physicians and an ethical environment that appeared inconsistent or unclear with respect to patenting medical inventions. As Pallin stated, "I used the law for my own purposes."<sup>20</sup>

But why did he choose to charge royalties and enforce his patent against Singer? The following interview excerpt<sup>21</sup> offers a few reasons:

"RENGARAJAN: You applied for the patent and you got the patent. Do you feel that was the recognition that you wanted? Or was there something more than that?

PALLIN: There was another slap in the face that I just egotistically couldn't tolerate. There was a young fellow who was brand new in our society from Vermont who went around taking credit for the incision,

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<sup>18</sup> Pallin interview, p. 12.

<sup>19</sup> Pallin interview, p. 23.

<sup>20</sup> Pallin interview, p. 11.



and lecturing and teaching courses in it. The patent attorneys that I was working with suggested that we might enforce the patent and collect royalties, and he might be a good one to start with.

RENGARAJAN: Was this your idea or was this your attorney's idea to go out there and enforce?

PALLIN: I'm not sure. We discussed it a lot. Probably it was a collective decision. Sounded like a fun thing to do. I'm not opposed to making money.

RENGARAJAN: No, no. I understand that.

PALLIN: So we did. We sued Jack Singer and the Hitchcock Clinic, which is a branch of the Lahey-Hitchcock Clinic. I don't know -- maybe the third-largest managed care organization in the country.

RENGARAJAN: So you targeted Singer for the reasons of: 1. He was part of a large organization that would have the resources to respond to this --

PALLIN: We figured if it was settled there, it would be settled. We wouldn't have to sue anybody else."

According to Pallin, both he and Singer knew each other's attitudes and did not preview the case in any way. Pallin's strategic decision to sue an infringer with adequate resources to wage a legal battle, coupled with his perception of Singer as an arrogant and rude man, led to a landmark lawsuit.

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<sup>21</sup> Pallin interview, p. 8.



#### IV. Ophthalmology for *Pallin v. Singer*

A basic understanding of the anatomy of the eye, cataract surgery techniques, and the historical development of cataract surgery will help in understanding the technical arguments raised in *Pallin v. Singer* and more broadly in understanding the context of inventive and innovative activity in ophthalmology.

##### Anatomy and normal function of eye

The eye is an extension of the nervous system (See Figure 1). It is a fluid- and jelly-filled structure containing many delicate annular and circular parts.<sup>1</sup> The globe, or eyeball, is divided into the anterior & posterior chambers in the front and the vitreous body in the back. The lens and its supporting apparatus separate the chambers from the vitreous body. The chamber at the front of the eye is the anterior chamber, and the chamber behind the anterior chamber, but in front of the lens, is the posterior chamber. The chambers are filled with a nutritious fluid called “aqueous” which flows from the posterior chamber to the anterior chamber. Aqueous is produced by the ciliary body, which lines the sides of the posterior chamber. The vitreous body is a transparent jelly-like substance.

The conjunctiva is a thin layer of clear tissue covering the front of the eye and overlies the sclera and cornea. The sclera is the white portion of the eye. The cornea is a circular clear structure at the front of the eye. The zone of separation between the sclera and cornea is the limbus which is a common anatomical landmark in cataract surgery. The cornea refracts, or bends, light rays entering the eye. The iris, which is an annular structure that determines our “eye color”, controls the amount of light that passes through the eye. Light rays pass through the cornea, iris, and then through the lens (See Figure 2). The lens sits in a capsule made of membrane tissue. Ligaments stretch and relax the lens in order to focus light<sup>2</sup> onto the retina, which is an array of nerve fibers that lines the back of the globe. The retinal fibers relay light signals to the brain where they are processed to form visual images.

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<sup>1</sup> Annular denotes ring-shaped.

<sup>2</sup> The lens, like the cornea, refracts light (bends light rays).





## Treatment of cataracts

A cataract is the cloudiness that occurs in the lens of the eye. Because the cataract blocks the passage of light from the front of the eye to the retina at the back of the eye, vision is obscured. Cataracts occur normally with aging.

### *Basic procedure and common complications*

Surgical removal is the standard treatment for cataracts. The surgeon begins by making an incision into the globe (Figure 3). He then enters the anterior chamber. The third step is to remove the clouded lens. The surgical procedure also includes placing an artificial intraocular lens (IOL) into the eye. After the cataract is removed and the IOL is placed, the incision is closed with sutures. If the surgery is a sutureless procedure, the incision is closed with simple apposition of the two sides of the incision.

Common complications include the typical complications of surgery, as well as surgically-induced astigmatism. Typical surgical complications include hemorrhage, infection, and problems with sutures. Sutures degrade over time, and when a suture breaks, one of the ends can stick up, creating a foreign body sensation for the patient. Sutures can also serve as the location for an abscess which can lead to infection. Astigmatism refers to a distortion of vision caused by a change in the shape of the cornea. An altered corneal shape leads to aberrant refraction of incoming light. Incisions and sutures can induce astigmatism by causing the cornea to stretch or to relax. As a general principle, the farther from the limbus (cornea) an incision or suture is placed, the less astigmatism that results.<sup>3</sup> This makes intuitive sense. If a suture is tied far from the limbus, and therefore far from the cornea, its pulling effect is spread over a greater area with less force applied to the cornea.

Cataract surgery can be varied by methods of incision, entry into the eye, cataract removal, IOL placement, and incision closure. The standard surgical technique at the time Pallin performed his first

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<sup>3</sup> The incision tends to cause the cornea to relax in that meridian. See Transcript of Interview with Dr. Marc Weitzman, Associate Professor of Ophthalmology, Yale University School of Medicine (Interview conducted by B. Rengarajan), June 26, 1998, p. 9. Hereafter referred to as “Weitzman interview.”



chevron incision was scleral tunnel surgery with phacoemulsification, IOL placement, and single-suture closure, as explained below.

### *Incision*

While on the operating table, the patient receives anesthetic eye drops to immobilize the eye for surgery. The surgeon sits next to the top of the patient's head. Thus, he views the eye in an upside-down manner (See Figure 4). The incision is specified by its clock position and distance from the limbus. The surgeon places the incision at the "12 o'clock" position<sup>4</sup> and begins with cutting a flap of conjunctival tissue in order to expose the underlying sclera and limbus. Subsequently, an incision is made into the sclera. Incisions come in different sizes, shapes, and internal constructions (Figure 4). One useful concept is that of chord length which is the distance between the ends of the incision.<sup>5</sup>

Over time, incisions have become less disruptive and less invasive. As mentioned previously, the more posterior the incision is placed (farther from the limbus), the less astigmatism is induced. Conversely, the more anterior the incision is placed (closer to the limbus), the more astigmatism is induced.<sup>6</sup> For a given incision shape, the larger the incision, generally the more astigmatism is induced.

### *Entry into the eye*

Classically, the lens was reached by entering through the cornea. As the field of cataract surgery progressed, the eye was entered through a scleral tunnel, also known as a scleral pocket incision. The tunneling technique was taken from glaucoma surgery and modified for cataract surgery. A tunnel is fashioned under the sclera from the incision site to the limbus. The tunnel can be straight and therefore

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<sup>4</sup> Location nearest the top of the patient's head.

<sup>5</sup> A semicircular incision, nine millimeters in length, can have the same chord length as a straight line incision, three millimeters in length. Chord length becomes relevant in discussions of inserting soft foldable intraocular implants.

<sup>6</sup> Anterior refers to the direction towards the front of the eye and posterior refers to the direction towards the back of the eye. The globe is a sphere with the cornea and limbus at the front. Thinking in three dimensions, the closer a point is to the limbus, the more anterior it is (assuming that a point on the cornea is not considered). The following phrases describing the location of an incision are equivalent: 3 mm posterior to the limbus, 3 mm behind the limbus, and 3 mm in back of the limbus.



constitute a one-plane incision, or it can be segmented into three sections and therefore constitute a three-plane incision (See Figures 5, 6, 7). At the limbus, the anterior chamber is entered.

The scleral tunnel allowed the surgeon to make the incision farther from the cornea, which minimized induced astigmatism. One potential problem with a long tunnel (>2.5-3mm) is “oarlock effect” which refers to difficulty in manipulating instruments and IOLs.

### *Cataract removal*

As the field has evolved, this step has become less crude and less invasive with less physical stress to the eye. Surgeons used to tear the lens out of the eye, but they now dissolve and gently aspirate the lens. From the anterior chamber, a capsulorhexis is performed (cutting a hole in the anterior portion of the lens capsule). The surgeon then inserts a phacoemulsifier, which is a device that emits ultrasound energy, into the capsule. The phacoemulsifier dissolves the nucleus, or inner part, of the lens. The surgeon then aspirates dissolved lens tissue from the eye. The capsule is left intact. The surgeon sometimes makes a second incision to insert a surgical instrument to help position the lens for phacoemulsification. Current experimental methods for removing cataracts include dissolving the clouded lens with an enzyme or a laser.<sup>7</sup>

### *IOL placement*

The surgeon passes the IOL through the scleral tunnel and into the empty lens capsule and then fixes it in position. Lenses can be chosen according to size, materials, and how they attach themselves to eye tissue. Hard lenses range in size from 5-7 mm in diameter. Soft lenses can be folded to 3.5 mm in diameter and then unfolded when in position.

### *Incision closure*

During surgery, the eye may have lost fluid pressure (hypotony) due to leakage from surgical manipulation and exposure. After IOL placement, the surgeon reinflates the eye with a basic salt solution

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<sup>7</sup> Weitzman interview, p. 1.



and then closes the incision with a single suture. Small incisions (3-4 mm or less) tend to self-seal.

Watertightness of the wound can be assessed by infusing fluid through a cannula into the anterior chamber at a desired pressure and watching for fluid leakage.

It is not clear what causes self-sealing in a sutureless incision. Pallin believes the scleral tunnel simply collapses due to the increased pressure of reinflation. Others believe a flap of corneal tissue, which is created upon entry into the anterior chamber, closes the incision tunnel when the eye is reinflated.

#### *Post-operative care*

Post-operative care involves monitoring and treating complications. The surgeon uses a slit lamp microscope to get a detailed view of the structures of the eye. Astigmatism is assessed with keratometry, keratotomy, and other methods. In keratometry, a small circle of light (about 3mm in diameter) is reflected off the cornea. Deviations in reflection indicate the roundness of the cornea. Keratotomy assesses reflection patterns with the use of concentric rings of light. Any remaining astigmatism is corrected with eyeglasses.

#### Development of cataract surgery

The different eras of cataract surgery can be defined by the method of removal of the lens: intracapsular, extracapsular, and phacoemulsification.<sup>8</sup>

#### *Intracapsular era*

One of the original incisions in cataract surgery was the vonGraefe incision in which the surgeon created a near 180-degree incision in the cornea to gain access to the lens (See Figure 4). The incision was on the order of 12-15 millimeters in length.<sup>9</sup> The surgeon used an extremely sharp blade to puncture the cornea on one side, traverse the anterior chamber, and exit on the other side. He then removed the blade

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<sup>8</sup> Weitzman interview.

<sup>9</sup> Declaration of Samuel L. Pallin, M.D. in Support of Plaintiff's Opposition to Defendants' Motion for Summary Judgment (filed 3/21/96), p. 3.





quickly which resulted in a filleted eye. The cornea was lifted up and out of the way, and the entire lens was removed by a number of methods. The surgeon could spoon or suction the lens out. Or he could use cryoextraction in which a freezing probe is applied to the lens, transforming it into an iceball which was easier to grip when he pulled the lens out of the eye. Complete removal of the lens and capsule, as this was, constituted intracapsular cataract extraction (ICCE). Any vitreous that leaked out of the eye was removed, and the wound was sutured, if sutures were available.

Many of the vonGraefe incisions were *de facto* sutureless incisions because sutures had not yet been invented or suture materials were unavailable. Those sutures that were available were medium to large-size sutures (6-0 and 8-0)<sup>10</sup> which were not fine enough to achieve watertight closure of the incision. Thus, the patient would be hospitalized for weeks with sandbags on either side of the head to keep the head still while the incision sealed. The vonGraefe was a difficult incision to master, and the first several hundred were marred by leakage. One severe complication of the vonGraefe and other incisions of that time was a disease entity called epithelial downgrowth that occurred in chronically leaking incisions. The epithelial tissue on the surface of the eye would enter the eye and grow inside, subsequently devastating intraocular contents. Post-operatively, patients were fitted with strong eyeglasses (12-15 diopters); without their glasses, they were functionally blind. IOLs had not yet been invented.

### *Extracapsular era*

As IOLs were developed, ophthalmologists converted from ICCE to ECCE, or extracapsular cataract extraction. In ECCE, only the lens was removed. The technique involves tearing an opening in the front of the capsule (capsulorhexis), expressing the nucleus of the lens, and leaving the capsule otherwise intact to support an IOL. ECCE did not require a 180-degree incision. A 110-120 degree incision with a chord length of 10-11 millimeters was sufficient. However, like ICCE, ECCE required 5-8 sutures for incision closure.

IOLs were developed after World War II by Harold Ridley in England. He noticed that some RAF fighter pilots had shreds of Plexiglass inside their eyes. The Plexiglass presumably came from the



canopies of the fighter planes. He observed that the material was very well tolerated. Concluding that the Plexiglass was inert, Ridley developed intraocular lenses made of Plexiglass in the 1940s and 50s. Considered radical, they did not achieve widespread use until the 1970s and 80s. Most ophthalmologists thought IOL implants were unsafe. Furthermore, ECCE, which is required for intraocular implants, is more difficult to perform than ICCE.

IOLs eventually became soft and therefore foldable. IOLs have developed with respect to materials (PMMA and silicone currently used), size, haptic design, and other features.<sup>11</sup>

### *Phacoemulsification*

While the ophthalmology field was switching from ICCE to ECCE, Dr. Charles Kelman was experimenting with phacoemulsification. The theory behind phacoemulsification is that ultrasound emitted from a vibrating piezoelectric needle dissolves the nucleus of the lens, which can then be aspirated. Phacoemulsification allowed the extraction of a cataract through a 3-4 mm incision because the phaco handpiece tip was only 3 millimeters in diameter.<sup>12</sup> It also facilitated the switch from anterior chamber to posterior chamber IOL implantation.<sup>13</sup> When phacoemulsification was sufficiently developed, ophthalmologists began to use foldable lenses because they were smaller and did not expand the wound as much as hard lenses did.

### *Advances in Cataract Surgery*

Advances in the field have built on previous discoveries, and many have been synergistic. Incisions have become smaller and less invasive. Implantable devices have become less alien to the body. Drugs have become more specific. And complications have been reduced in frequency and magnitude.

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<sup>10</sup> The higher the size number, the finer the suture (less cross-sectional area). Today, 10-0 sutures are routinely used in cataract surgery.

<sup>11</sup> PMMA is an abbreviation for polymethylmethacrylate, an acrylic substance. The first IOLs used iris support. IOLs were later fixated in the anterior chamber, and still later in the posterior chamber. In the 1980s, IOLs were attached to a minimally disrupted capsular bag (a capsule on which capsulorhexis was performed). See p. 7 in Sutureless Cataract Surgery / An Evolution Toward Minimally Invasive Technique, (Gills, P.; Martin, R.; and Sanders, D. (eds.)) Thorofare, NJ: Slack Incorporated. 1992. 200pp. Hereafter referred to as Sutureless.

<sup>12</sup> Sutureless, p. 9.



Advances in surgical technique and IOL technology that have led to minimally invasive cataract and IOL surgery<sup>14</sup> include, in chronological order:

- Iris fixated IOL
- Anterior chamber IOL
- Anterior chamber phaco
- Posterior chamber phaco
- Posterior chamber IOL
- Scleral tunnel incisions
- In situ phaco techniques
- Foldable silicone IOLs
- Capsulorhexis
- Horizontal suture closure (Devised by Dr. John Shepherd)
- Sutureless closure

Advances in surgical technique, IOL technology, and suturing that have led to a decrease in astigmatism include, in chronological order:

- Smaller sutures (10-0 and 11-0)
- Phacoemulsification (as incision decreased from 10mm to 6mm)
- Deep suturing technique
- Scleral tunnel incisions
- Corneal relaxing incision (Equatorial incisions in the cornea)
- Horizontal suture closure (Devised by Dr. John Shepherd)
- Hard lenses to soft foldable lenses (6mm to 3-4mm incisions)

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<sup>13</sup> Sutureless, p. 8.



Although sutureless incisions were new to the ophthalmology field in the early 1990s, classical incisions were *de facto* sutureless. The advantages of sutureless incisions include the avoidance of suture complications, such as induced astigmatism and abscess, and savings in cost and time for the patient and surgeon. The disadvantages include reduced maneuverability and reduced visibility for the surgeon.<sup>15</sup>

With posterior placement of the incision, the phacoemulsification handpiece needs to traverse a greater distance to reach the capsule which can result in “oarlock” effect, which is often experienced with tunnel lengths of 3-4 millimeters. The long scleral tunnel with entry of instruments can cause corneal folds which obscure a clear view of the anterior chamber and lens. Only time will tell how significant sutureless incisions are to cataract surgery.

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<sup>14</sup> Sutureless, p. 8, 11.

<sup>15</sup> Sutureless, p. 47.





## V. Patents: a subset of intellectual property instruments

### Utility Patents

Intellectual property embodies a legal conception referring to ownership of intangible property. The owner of intellectual property controls the disposition of something that is intellectually appreciated and understood.<sup>1</sup> The U.S. Constitution empowers Congress “To promote the progress of Science and the useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”<sup>2</sup> The traditional interpretation regards “useful Arts” as applied technology and “Science” as general knowledge.<sup>3</sup> Copyright law promotes science, and patent law promotes the useful arts. The U.S. government uses a number of instruments to protect intellectual property including copyrights, trademarks, plant patents, plant variety protection certificates, semiconductor designs, and utility patents with varying requirements and monopoly terms.<sup>4</sup> The utility patent is commonly referred to as a “patent.”

Congress passed the first patent statute in 1790, significantly revising it only in 1793, 1836, and 1952. In theory, patents promote technological progress by giving inventors an incentive to disclose their inventions to the public. Patents allow inventors to exclude others from making, using, and selling an invention for twenty years after the filing date of the patent application.<sup>5</sup> The main aim is not to reward the inventor, though this may occur, but rather to enable the public to take advantage of the disclosed

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<sup>1</sup> Weil, V. and Snapper, J. “Introduction,” in Owning Scientific and Technical Information: Value and Ethical Issues, Weil and Snapper (eds.), New Brunswick: Rutgers University Press. 1989, p. 3.

<sup>2</sup> U.S. Constitution, Article I, Section 8, Clause 8.

<sup>3</sup> Eisenberg, R. “Proprietary Rights and the Norms of Science in Biotechnology Research,” 97 *Yale Law Journal*. 1987, pp. 185-6.

<sup>4</sup> The Plant Patent Act of 1930 is codified in Chapter 15 of Title 35 of the U.S. Code. According to 35 U.S.C. 161, plant patents can be obtained by “[w]hoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state.” The Plant Variety Protection Act of 1970, codified in 7 U.S.C. 2321-2583, established protection for sexually-reproduced plant varieties that meet the criteria of distinctness, uniformity, and stability. The Plant Patent Act of 1930 was restricted to asexual plant reproduction. The Semiconductor Chip Protection Act of 1984, codified in 17 U.S.C. 912, established protection for semiconductor chip designs, or mask works.

<sup>5</sup> The term of a patent had previously been 17 years. A provision of the General Agreement on Tariffs and Trades, effective June 1995, increased the term to 20 years from the date that an application is filed.



invention.<sup>6</sup> Disclosure is assumed to accelerate progress by allowing inventors to build upon disclosed inventions, thus avoiding duplication in effort. The patent document, which contains the patent claims and specifications, achieves disclosure.

Although “invention” and “innovation” are often used synonymously, they are different. In one author’s view, an invention is the practical application of an idea.<sup>7</sup> More than a concept but less than a fully worked-out product or method, an invention takes the form of a prototype. An innovation is the debugged or for-sale version of the invention. Patents reward inventions. In this paper, “invention” and “innovation” will be used interchangeably in order to avoid confusion.

In the United States, patents are granted to persons who are first to invent patentable items rather than to those who are first to file patent applications. An inventor has a grace period of one year after devising his invention to file a patent application. During that year, he may disclose and use his invention. After one year, another person may file a patent application on the invention if the original inventor has not done so. Thus, the patentholder need not be the inventor. In countries with a first-to-file system, the inventor has no grace period. The first person to file a patent application on a particular invention is the first eligible for the patent.

To be patented, an invention must meet a number of statutory requirements. According to Title 35 of the U.S. Code (Patents),<sup>8</sup> “any new and useful process, machine, manufacture, composition of matter, or any new and useful improvement thereof” is eligible for a patent. Practically speaking, patents are granted for products, methods, or methods of use (of a product).<sup>9</sup> Exceptions to patentable subject matter include printed matter, methods of doing business, and naturally occurring substances. Inventors generally cannot patent ideas, laws of nature, abstract principles, and physical phenomena, but they can patent

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<sup>6</sup> Kintner, Earl W. and Lahr, Jack. An Intellectual Property Law Primer. Clark Boardman Company, Ltd.: New York, NY. 1982, p. 11.

<sup>7</sup> Merges, R. “Commercial Success and Patent Standards: Economic Perspectives on Innovation,” 76 *California Law Review*, 1988. P. 807.

<sup>8</sup> 35 U.S.C. Section 101.

<sup>9</sup> Processes, such as a chemical synthesis or the genetic engineering method, comprise the means to produce a certain result.” A manufacture is an inventive human-made structure. A machine is a distinctive means for achieving a particular result. A composition of matter, such as a metal alloy, or a genetically engineered organism, consists of a combination of individual elements that comprise a compound. Improvements comprise modifications and extensions of inventions. See Miller, Arthur R. and Davis,



applications of them.<sup>10</sup> Thus, no one could patent the Starling curves for heart performance, but an inventive artificial heart based on these principles could be patented.

To qualify for a patent, eligible subject matter must be useful, novel, and nonobvious. A patentable invention must possess value in an industrial or commercial sense.<sup>11</sup> Usefulness in academic research, if not accompanied by a possible industrial or commercial application, does not constitute utility under patent law.<sup>12</sup> An invention should be useful, but it need not meet a particular quantity of usefulness.<sup>13</sup>

The novelty requirement of patent law specifies that the invention be new to the public domain.<sup>14</sup> If previous literature in the field describes the invention or the public previously knew of the invention ("prior art"), a patent will not ensue. However, to preclude patenting, prior art must so substantially describe the invention that it achieves the enablement aim of patent law, which requires that a written disclosure enable one skilled in the art to make and use the invention as claimed.<sup>15</sup> Merely foreshadowing a future invention is insufficient. However, in order to anticipate an invention and therefore to preclude patenting or to nullify an existing patent, prior art must anticipate all claims in the patent application or in the patent. That is, a prior invention must possess all features of the invention under consideration. As a hypothetical example, a glider craft and a locomotive engine, individually or together, do not preclude patenting of a jet airplane because each of the prior inventions did not possess all features of the invention under consideration. Also, in order to qualify as prior art (that is, to exist in a legal sense), the inventor must have reduced his idea to practice (created and used the product or process) and not have concealed, abandoned, or suppressed his work.

The nonobviousness requirement is considered the most important standard of patentability.<sup>16</sup> A patentable invention must be nonobvious to an ordinary person skilled in the art (the average worker in the

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Michael H. Intellectual Property / Patents, Trademarks, and Copyright in a Nutshell. West Publishing Co.: St. Paul, MN. 1983, p. 29.

<sup>10</sup> Miller and Davis, p. 25, 31

<sup>11</sup> 35 U.S.C. Section 101.

<sup>12</sup> See *Brenner v. Manson* 383 U.S. 519 (1966). Cited in Miller and Davis, p. 67.

<sup>13</sup> *Anderson v. Natta* 480 F.2d 1392 (C.C.P.A. 1973). Cited in Miller and Davis, p. 65.

<sup>14</sup> 35 U.S.C. Section 102.

<sup>15</sup> Enablement specified in 35 U.S.C. Section 112.

<sup>16</sup> 35 U.S.C. Section 103.



field) at the time the invention was developed. Case law has contributed a set of secondary considerations which may be used to assess nonobviousness.<sup>17</sup> These considerations -- commercial success, long-felt but unsolved needs, and failure of others to invent – take into account the marketplace. Thus, if an inventor devises an invention which is obvious but meets secondary considerations, he may be granted a patent.

### *Patent adjudication*

Case law and internal Patent Office decisions supplement the patent statutes. As *Pallin v. Singer* moved forward, many facets and doctrines of patent law were advanced to support and refute arguments. Of relevance to the case is the distinction between infringement and anticipation, and the relationship of patent claims and specifications. Infringement constitutes making, selling, or using an invention on or after the date on which it is patented. Purchasing a license from the patentholder would waive infringement. Anticipation involves the creation and disclosure of an invention by one inventor before the creation of the same invention by a second inventor who may possess a patent or be applying for one. The scope of a patent is determined by its claims. One important concept is that the specifications (the preamble and background text) of a patent narrow the scope of the claims. They can never widen the scope of patent claims.

Two noteworthy items of case law are the doctrine of equivalents and the doctrine of experimental use. Used commonly in chemicals cases, the doctrine of equivalents protects the patentholder from pirates who can easily bypass the literal scope of a patent's claims by making insignificant changes and then make and use an invention that "performs substantially the same function in substantially the same way to obtain the same result."<sup>18</sup> An example might be a pirate who substitutes a methyl group for an ethyl group in a large hydrocarbon molecule and deems it a new invention. The experimental use doctrine allows for making and using a patented invention without a license, if for the purposes of experimentation.<sup>19</sup> Thus,

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<sup>17</sup> See *Graham v. John Deere Co.* 383 U.S. (1966).

<sup>18</sup> *Graver Tank & Mfg. Co. v. Linde Air Products Co.* 339 U.S. (1950) cited in Noonan, W. "Patenting Medical Technology," *The Journal of Legal Medicine*, 11: 263-319. 1990, p. 275. article (1990), p. 275.

<sup>19</sup> *Manville Sales Corp. v. Paramount Systems, Inc.* 917 F.2d 544 (Fed. Cir. 1990) cited in Garriss, J. "The Case for Patenting Medical Procedures," *American Journal of Law and Medicine*, 22: 87-108. 1996, p. 88, Footnote 31.





someone who was merely experimenting with Pallin's patented incision technique but not using it for commercial purposes would not be deemed an infringer of Pallin's patent.

#### Patent Application Process<sup>20</sup>

The patent applicant submits his application, which consists of the applicant's claims and his disclosure of prior art, to the U.S. Patent and Trademark Office (PTO). The PTO first classifies and then sends the application to an examiner in the appropriate art unit. The examiner may receive the application as much as six months after the PTO received it. The genre or type of invention described in the application determines where it is sent within the PTO. PTO examining groups, which on average consist of 140 examiners, are grouped into six technology centers. Groups contain multiple art units, each of which typically consists of 12 examiners. The six technology centers are biotechnology; chemistry; computers; electrical products and physics; construction, farm equipment, heavy machinery; and mechanical products. Pallin's patent application was examined in art unit 336 which is part of the medical devices group in the mechanical products technology center.

The examiner consults in-house experts (typically primary examiners who are more experienced), searches the patent database, searches journal databases in an effort to amass literature relevant to assessing patentability, and then checks for any similar patents pending. In-house consultations are routine. Outside experts are not consulted because it would breach confidentiality. In-house library staff can also perform journal searches. The examiner then makes a decision about prior art and patentability.

If the examiner files an office action (e.g. deems some or all claims unpatentable), the patent applicant and his attorney have three months in which to respond. After this response is given, the examiner has two months to reply to the response. A give-and-take occurs between the two parties until the examiner renders a final decision. If the examiner rejects an application and the inventor and his attorney disagree with that decision, they can file an appeal with the PTO Board of Patent Appeals and

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<sup>20</sup> Transcript of Interview with U.S. Patent and Trademark Office (PTO) Examiner (Interview conducted by B. Rengarajan), April 13, 1998. Hereafter referred to as "PTO examiner interview." The examiner preferred not to be identified.



Interferences. If the Board affirms the examiner's decision, the inventor can appeal to the Court of Appeals for the Federal Circuit and then to the U.S. Supreme Court.

If an individual believes an invention is not patentable and the patent examination has not been completed, he can protest the application.<sup>21</sup> If a patent has already issued on the invention, he can show prior art and request a reexamination.<sup>22</sup> An individual can file a request for reexamination at any time during the term of the patent. The reexamination venue avoids litigation.

As of summer 1998, average processing time for a patent application was about 18 months, but efforts are underway to reduce processing time to one year or less, especially in the biotechnology area.<sup>23</sup>

### Medical Procedure Patents

The patent statutes do not specifically address medical procedures. Thus, an inventor can patent a medical procedure that meets the statutory requirements of patentability. Only one categorical exclusion of patentable subject matter exists. Inventions which jeopardize national security, such as atomic and nuclear weapons, cannot be patented.<sup>24</sup> However, any other invention, including genetically-engineered organisms, can be patented.<sup>25</sup> Although the patent statutes do not specifically address medical procedures, cases within the Patent Office, as well as cases in the courts, have established relevant precedent.

Although *Pallin v. Singer* sparked public debate over the ethics of patenting medical procedures, this controversial issue has been raised before. Medical procedures are patentable, but for about 150 years after the first patent statute was enacted, diagnostic and therapeutic methods were typically not considered patentable.<sup>26</sup> They often did not meet the criteria set forth in the patent statutes. Nevertheless, the patenting of medical products and procedures has engendered strong emotions.

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<sup>21</sup> Protest as per 37 CFR 1.291. (Code of Federal Regulations). If the PTO keeps patent applications secret, how would an individual know enough about an invention to consider it unpatentable? The patent applicant may have disclosed his invention before submitting the application or during the examination process.

<sup>22</sup> Reexamination request as per 37 CFR 1.5108.

<sup>23</sup> Transcript of Interview with PTO Examiner, April 13, 1998.

<sup>24</sup> 35 U.S.C. 181.

<sup>25</sup> *Diamond v. Chakrabarty*. 447 U.S. 303 (1980). The Supreme Court noted that Congress had intended patentable subject matter to "include anything under the sun that is made by man."

<sup>26</sup> Portman, R. White paper: "Legislative Restriction on Medical and Surgical Procedure Patents Removes Impediment to Medical Progress," p. 3.



In the mid-1800s, the Goodyear Tire Company patented the process of vulcanization, which made rubber stronger and more durable, and in the 1860s and 70s, dentists began to substitute vulcanized rubber for wood in making dentures.<sup>27</sup> Goodyear filed a multitude of infringement lawsuits against dentists. Dental associations rallied to help finance defendants' lawsuits. The lawsuits earned significant royalties until an angry dentist murdered Josiah Bacon, the Treasurer of the Goodyear Dental Vulcanite Company and prosecutor of infringement cases. The infringement cases involved medical products rather than diagnostic or therapeutic methods, but they caused a public stir. The patenting of aspirin and of diphtheria antitoxin also met with harsh criticisms deploring commercial gain at the expense of the afflicted.<sup>28</sup>

One of the first U.S. patents for medical methods was granted in 1846 for a method of using inhaled ether for surgical anesthesia. The patent was invalidated in 1862 on the grounds that the method did not constitute an invention under the patent statutes.<sup>29</sup> The court stated that the anesthesia method did not constitute the discovery of a new product or a new use of the product. The court further noted that methods are not patentable if the process exists as a natural function of the body:

“A discovery may be brilliant and useful, and not patentable. No matter through what long, solitary vigils, or by what importunate efforts, the secret may have been wrung from the bosom of Nature, or to what useful purpose it may be applied. Something more is necessary. The new force or principle brought to light must be embodied and set to work, and can be patented only in connection or combination with the means by which, or the medium through which, it operates. Neither the natural functions of an animal upon which or through which it may be designed to operate, nor any of the useful purposes to which it may be applied, can form any essential parts of the

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<sup>27</sup> Noonan, W. “Patenting Medical and Surgical Procedures,” *Journal of the Patent and Trademark Office Society*, pp. 651-64. August 1995, p. 652-3. Noonan cites Ring, “The Rubber Denture Murder Case: The Story of the Vulcanite Litigations,” 3 *Bulletin of the History of Dentistry*, 1984.

<sup>28</sup> Noonan (1995), p. 653.

<sup>29</sup> *Morton v. New York Eye Infirmary* 17 F. Cas. 879 (S.D.N.Y. 1862), Case number 9,865.



combination, however they may illustrate and establish its usefulness.”<sup>30</sup>

In 1883, in *Ex parte Brinkerhoff*, a case within the Patent Office, the Commissioner of Patents rejected a patent application for a method of treating hemorrhoids by injecting a medication.<sup>31</sup> The Commissioner wrote:

“The methods or modes of treatment of physicians of certain diseases are not patentable; they are discoveries which may in a majority of cases under certain conditions accomplish certain results, but no particular method or mode of treatment under all circumstances, and in all cases will produce upon all persons the same result, and, hence to grant a patent for a particular method of treatment would have a tendency to deceive the public by leading it to believe that the method therein described and claimed would produce the desired result in all cases. . . .It should be reasonably certain in every case that the invention sought to be patented will produce a certain result.”<sup>32</sup>

The patent was not rejected on the basis of sympathy for the afflicted but rather to deny support to the belief that medical therapy is predictable and certain. The Commissioner viewed medical therapy as speculative. This decision was observed for the next the next fifty years with only a few patents on therapeutic methods issued.<sup>33</sup>

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<sup>30</sup> Morton v. New York Eye Infirmary. Quoted in Portman, pp. 4-5, Footnote 8.

<sup>31</sup> *Ex parte Brinkerhoff* (1883).

<sup>32</sup> 24 Comm’r MS Decision 349 (1883) 27 *Journal of the Patent Office Society*. Quoted in Portman, p. 5, Footnote 10. And cited in Noonan (1995), p. 653.

<sup>33</sup> *Ex parte Wappler* (26 U.S.P.Q. 191, Pat. Off. Bd. App. 1935) was an appeals case in the Patent Office in which the Board of Patent Appeals overturned an examiner’s rejection of a patent for a method of shrinking living tissue. In *Ex parte Kettering* (35 U.S.P.Q. 342, Pat. Off. Bd. App. 1936), the Board overturned an examiner’s rejection for a patent on a method of inducing fever in the body, apparently in order to treat paresis. In *Dick v. Lederle Antitoxin Laboratories*, a state court upheld a patent on a method





In 1902, a bill to exclude medical and surgical procedures from patentable subject matter was introduced in the U.S. Congress.<sup>34</sup> Accompanied by a positive committee report, the bill went to the floor of the House. But the House did not take any action. A similar bill, introduced the following year, met with the same fate.

In 1951, in the case of *Martin v. Wyeth*, the court addressed the ethics of doctors and the ethical objections to patents on medical discoveries:

“Doctors and surgeons have seldom thought it desirable to try to patent their new procedures for human relief. . . . The professional ethics of doctors and surgeons are more consistent with the widespread use of their medical and surgical discoveries for the benefit of mankind than in obtaining a monopoly to control their discoveries for personal commercial advantage. In this respect it would seem also that public interest is involved here.”<sup>35</sup>

Although the court stated ethical objections to patenting medical procedures, these discoveries were still deemed patentable under the patent statutes.

In 1954, the Patent Office explicitly rejected *Ex parte Brinkerhoff* in its decision in *Ex parte Scherer*. Scherer, the inventor, had applied for a patent on a method of injecting fluids into the human body. The examiner correctly rejected the patent application on the basis of the ruling in *Brinkerhoff*. However, the Patent Office Board of Appeals decided that patenting a method which treats the human body but has as its object some medical or surgical purpose is patentable. The Board of Appeals wrote:

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of inoculating people against scarlet fever, rejecting the notion that a method that operated on the body was unpatentable. See Portman, pp. 6-7 and Noonan (1995), p. 654.

<sup>34</sup> H.R. 12451, March 12, 1902. A similar bill, H.R. 13679, was introduced the following year. Cited in Noonan (1995), p. 654.

<sup>35</sup> *Martin v. Wyeth* 96 F. Supp. 689 (D.Md. 1951) aff'd 193 F.2d 58 (4<sup>th</sup> Cir. 1951). Quoted in Noonan (1995), p. 655.



“The only specific reason given [for the prohibition] is uncertainty of results, which does not appear to be a valid reason for categorically refusing all methods, and which reason is more properly considered under the question of utility which is a separate and distinct requirement for patentability. To the extent that *Ex parte Brinkerhoff* holds or implies that all medical or surgical methods are unpatentable subject matter merely because they involve the human body, that decision is expressly overruled.”<sup>36</sup>

However, the sole dissenter on the Board wrote that in the preceding 150 years it appeared that no court had supported patent claims on alleviating disease. But in the decades after *Scherer*, the Patent Office has issued many medical procedure patents (See Table 1).

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<sup>36</sup> *Ex parte Scherer* 103 U.S.P.Q. 107 (Pat. Off. Bd. App. 1954). Quoted in Portman, p. 8. According to William Noonan, by the middle of the 20<sup>th</sup> century, medical research had become costly and the Patent Office began to view medical therapy as having greater scientific basis than in the past.<sup>36</sup> In 1948, the AMA recognized the need for intellectual property protection and changed its previous position which held that medical patents were unethical. Noonan (1995), p. 655.



## VI. Who is Singer?

So it was that the first time in U.S. history one physician was suing another physician over infringement of a medical method patent, one graduate of the State University of New York Downstate Medical Center was suing another graduate of the same institution.

### Biographical Sketch<sup>1</sup>

Jack A. Singer was born November 23, 1955 in Brooklyn, New York. After graduating *summa cum laude* from the State University of New York in 1977 with a B.S. degree, Singer attended the State University of New York Downstate Medical Center where he earned an M.D. degree in 1981. Although he had been interested in pursuing cardiology, he decided to go into ophthalmology after observing eye surgery during his third year of medical school. He enjoyed working with his hands and knew he would enter a surgical specialty. Singer completed a flexible internal medicine internship at Long Island College Hospital in Brooklyn, New York in 1982 and then pursued ophthalmology residency at the Friedenwald Eye Institute at Maryland General Hospital in Baltimore.

After residency, Singer and his wife wished to move back to the northeast and settle in a rural area. At the time, the Hitchcock Clinic, a multi-specialty physician practice, was looking for someone to establish a regional site in Randolph, Vermont. Singer took the position and has been there ever since. Board-certified in ophthalmology, Singer limits his practice to cataract and refractive surgery.

An Assistant Professor of Clinical Surgery (Ophthalmology) at Dartmouth Medical School and Chief of Surgery at the Gifford Medical Center, Singer holds numerous professional memberships and faculty appointments. He has given numerous video and lecture presentations, published scientific papers, and led skills workshops on topics such as hydrodissection, phacoemulsification, IOL implantation, and wound construction. Singer has won many professional society awards, including ASCRS film festival awards. Singer has also been involved in clinical development activities, including FDA investigations on IOLs and lens insertion / iris forceps, development of the “Cobra Phaco Tip,” and development of the



frown incision. Of note, since January 1993, he has been a peer reviewer and a member of the editorial board of the *Journal of Cataract and Refractive Surgery*, the very same journal that refused publication of Pallin's chevron incision.<sup>2</sup>

### Evolution of the Frown Incision

Singer had been looking for an incision that would admit hard lenses but possess the benefits of a small incision. Remembering a presentation by Dr. Stephen Siepser on the radial transverse incision, Singer conceived of what was to be named the "frown" incision:

"I hypothesized that radializing each half of a scleral pocket incision by curving it away from the corneal limbus would limit the amount of wound slide and against-the-rule drift in astigmatism, while permitting insertion of PMMA IOLs with up to 7mm optics and closure with a horizontal mattress suture, limiting initial with-the-rule astigmatism."<sup>3</sup>

At its most anterior point (closest to the front of the globe), the incision was 1.5 millimeters from clear cornea, which would fall within the range specified by the Pallin patent for a curvilinear incision which curves away from the limbus.<sup>4</sup> Unlike Pallin, Singer used a suture to close his incision wounds.<sup>5</sup> In 1991,

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<sup>1</sup> Curriculum Vitae of Jack A. Singer, M.D.; Transcript of Interview with Dr. Jack Singer at his clinic in Randolph, Vermont (Interview conducted by B. Rengarajan), June 26, 1998, p. 1. Transcript hereafter referred to as "Singer interview."

<sup>2</sup> There is no evidence to suggest Singer played any part in the rejection of Pallin's initial article submission, although this author did not specifically research this notion. It is assumed that Singer is still a member of the editorial board. Information gleaned from Curriculum Vitae of Jack A. Singer, M.D., p. 2. CV was submitted in the period 1994-96 as an appendix exhibit in legal briefs used in *Pallin v. Singer*.

<sup>3</sup> Singer, J. "Frown incision for minimizing induced astigmatism after small incision cataract surgery with rigid optic intraocular lens implantation," *Journal of Cataract and Refractive Surgery*, Vol. 17 Supplement, 1991, p. 678. Hereafter referred to as "Singer Supplement article." "Against-the-rule" and "with-the-rule" astigmatism refer to curving of the cornea in the horizontal and vertical meridian respectively.

<sup>4</sup> See chapter entitled "Pallin's Invention and Patent."

<sup>5</sup> Singer used a 10-0 single nylon suture. 10-0 represents a fine suture (has a small cross-sectional diameter).





Singer reported the results of a one-year prospective trial he conducted in which he found less induced astigmatism with the frown incision than with the standard scleral pocket incision.<sup>6</sup>

Singer first published his frown incision in *Ocular Surgery News* in the same issue that an article on the chevron incision was printed.<sup>7</sup> He had written the article after doing his second case, but the news journal held the article until the August 15, 1990 issue which contained a number of articles on incision techniques. It was the first Singer had known of the chevron incision. Singer notes that he developed the frown incision to eliminate the problem of surgically-induced astigmatism, not to eliminate sutures.<sup>8</sup>

### Beliefs, Values, and Perceptions in Medicine

#### *Ophthalmologic invention and innovation*

Singer deems advancements in technology and the procedures that accompany them to be the most exciting change in medicine.<sup>9</sup> In his view, ophthalmology has advanced faster than most other medical specialties. Singer believes few advances in medicine are revolutionary. He includes phacoemulsification and intraocular implants among these in the last half century.<sup>10</sup> He sees advances such as John Shepherd's horizontal suturing technique, which allowed reduction to one suture for closing incisions, as important but not as revolutionary. Shepherd's technique allowed suturing parallel to the corneal limbus which eliminated radial forces on the cornea and therefore reduced or eliminated astigmatism.<sup>11</sup> Singer places the next advance, suturelessness, in perspective:

“Just about all of the advances in procedures and methods of medical  
and surgical treatment are evolutionary. Advances build on one

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<sup>6</sup> Singer Supplement article, p. 684.

<sup>7</sup> Singer interview, p. 9.

<sup>8</sup> Singer interview, p. 3.

<sup>9</sup> Singer believes one of the most exciting current trends is the merging of cataract and refractive surgery procedures which will allow simultaneous removal of cataracts and improvement of refractive errors (e.g. astigmatism, nearsightedness, farsightedness) to yield better vision than the patient had preoperatively. Singer interview, p. 1.

<sup>10</sup> Singer interview, p. 2.

<sup>11</sup> Singer interview, p. 2.



another. And, it's through the free exchange that this evolves. Very few are revolutionary, . . . smaller changes in technique, such as reducing the number of stitches and finally eliminating the stitches are evolutionary. . . .I have come across references to the self-sealing ability of cataract incisions for over a hundred years. Before sutures were available in the 1800s, there were no sutures used for cataract extraction."<sup>12</sup>

Singer is correct to point out that suturelessness existed before the advent of sutures, but intentionally achieving suturelessness when sutures are available is a feat, be it revolutionary or evolutionary.

#### *Opposition to patenting of medical methods*

Singer believes that as medical students mature into physicians they become interdependent. By sharing information and resources freely, they improve patient care. However, in his view, the patenting of medical procedures threatens to halt this tradition and ultimately to compromise physician autonomy and the doctor-patient relationship, to increase health care costs, and to worsen the quality of medical care. Singer expressed these views in a presentation at the ASCRS Symposium on Cataract, IOL, and Refractive Surgery on April 10, 1994 in Boston.<sup>13</sup> In explaining the culture of open exchange of information in medicine, Singer appealed to the ethical sensibilities of his audience by quoting from the AMA's Principles of Medical Ethics, which states that physicians should share knowledge, skills, and techniques with colleagues and should not intentionally withhold such information for personal gain.<sup>14</sup> Singer feels that patenting medical procedures will stem the flow of information and hurt patients when inventors withhold information about an invention until the patent issues or when physicians hesitate to speak about which techniques they use for fear that they might be accused of patent infringement.

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<sup>12</sup> Singer interview, p. 2.

<sup>13</sup> Singer, J. "The Free Exchange of Medical and Surgical Knowledge." Revised January 1996. Presentation at the ASCRS Symposium on Cataract, IOL, and Refractive Surgery on April 10, 1994 in Boston, MA. Hereafter referred to as Free Exchange.

<sup>14</sup> Free Exchange, p. 7.



Another potential problem Singer raises is that of opportunists obtaining patents on inventions that they did not invent by skimming off the “vast pool of freely exchanged and currently unpatented medical knowledge.”<sup>15</sup> Singer is probably exaggerating the problem. If information about an invention is freely available, which constitutes prior art, then the invention is not novel under patent law and therefore will not be granted a patent. Thus, an opportunist would find nothing to patent. If an individual takes ideas in the public domain and creates an inventive application of them -- that is, he reduces the ideas to practice -- then the invention might be patentable. But this is a standard manner of inventing. Thus, it is not clear what type of scenario Singer envisions.

Singer thinks patenting of medical methods will compromise physician autonomy and the doctor-patient relationship. In his view, physicians would have to perform weekly patent searches to check that the techniques they are using or plan to use are not patented. Furthermore, they would not use particular procedures on patients for fear of patent infringement suits. Singer testified before Congress:

“For the average physician, medical method patents are like ticking time bombs, just waiting to explode into a patent infringement action at any time.”<sup>16</sup>

Singer paints a chilling image of medical practice where physicians tread lightly in navigating an intellectual property minefield:

“The result could be dozens of patents for just one surgical procedure and thousands of new medical method patents in total. After all, if Dr. Pallin’s technique is patentable, so is every other new variation on every possible medical and surgical procedure. Even where the

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<sup>15</sup> Free Exchange, p. 10 and “Hearing before the Subcommittee on Courts and Intellectual Property of the Committee on the Judiciary / House of Representatives / One Hundred Fourth Congress, First Session on H.R. 1127: Medical Procedures Innovation and Affordability Act and H.R. 2419: Inventor Protection Act of 1995,” October 19, 1995. U.S. Government Printing Office: Washington, p. 46. Hereafter referred to as “Hearing.”



existence of patents is unknown, or where patent applications may be pending outside public view, physicians, to avoid inadvertent infringement, will inevitably become more conservative about using new procedures and speaking publicly or writing about them.”<sup>17</sup>

Either Singer exaggerates when he states that “every other new variation” will be patented or he believes Pallin’s patent is a simple variation that is not worthy of a patent. A patent should issue on a “new variation” only if patentability criteria are met. Nevertheless, some doctors may choose not to use a certain technique in order to avoid paying a license fee.

Along these lines, Singer believes patenting of medical methods will inflate health care costs with licensing fees for using and teaching procedures, patent searches, patent applications, patent litigation fees, and inhibition of free exchange of information between physicians.<sup>18</sup> This will increase medical education and liability insurance costs and threaten academic medical centers’ mission of generating and sharing knowledge.

Singer is also concerned that patentholders can restrict unbiased evaluation of their procedures by peer reviewers.<sup>19</sup> Patents could give an impression of efficacy that is unwarranted. Singer notes that many physicians advertise “patented” techniques which possess little or no scientific merit.

Singer’s final objection to patenting medical methods strikes at the heart of the patent system. Singer believes the patent system does not achieve its objectives in the medical sciences. Singer differentiates what promotes advancement and disclosure in medical sciences – intellectual curiosity and creativity, professional recognition, increased patient referrals, ethical duties -- from what promotes advancement in other fields of inventive activity.<sup>20</sup> Furthermore, he believes medical and surgical procedures constitute natural principles and therefore cannot be patented under the patent statutes:

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<sup>16</sup> Hearing, p. 45.

<sup>17</sup> Hearing, p. 45.

<sup>18</sup> Free Exchange, pp. 11-12.

<sup>19</sup> Free Exchange, p. 11.

<sup>20</sup> Free Exchange, pp. 12-13.





“The basic distinction between discovery and invention is that natural laws and *principles* have always existed, and can be discovered & understood, but they *cannot be invented*. In fact, many new methods of medical & surgical treatment are *principles* discovered through the *free and open exchange of ideas*, **not inventions** to be owned. This is the basic underlying problem in the way current U.S. patent law is interpreted. Our government is granting exclusive ownership, for a 20 year term, to the discovery of principles of medical and surgical treatment, which will threaten to end the free and open exchange of information that led to these discoveries. . . .It appears Congress needs to define patent law with respect to medical and surgical treatment methods for those individuals who choose not to distinguish what is currently legal from what promotes progress in the medical sciences.”<sup>21</sup>

Singer calls for a legislative remedy because he sees irreconcilable differences between the patent system and medical culture. Unlike most opponents of patenting medical methods, Singer addresses not only the results of the applying the law but also the suitability of the law to the medical profession:

“The free exchange of medical and surgical methods cannot coexist with the monopoly-dependent exchange of the patent system. Two entirely different sets of values and incentives will work against each other, and only one will survive. I hope the free exchange system will prevail, for it places the needs of our patients, the medical profession, and the health and welfare of our society first. The only individuals who stand to benefit from a monopoly dependent medical method

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<sup>21</sup> Free Exchange, p. 5.



exchange system are medical method patent owners and their lawyers.”<sup>22</sup>

Singer says that the Hippocratic Oath teaches that physicians should teach their art “without fee or stipulation.”<sup>23</sup> Thus, Singer and Pallin may not differ in their views on the exchange of knowledge, skills, and techniques in medicine, although Pallin used the law to his advantage. Singer’s final appeal lays in looking at the foundation of the patent system – not the PTO, patent case law, or the patent statutes, but the United States Constitution:

“Medical method patents simply cannot serve to promote the progress of medical science and useful surgical arts, and therefore in my opinion, is inconsistent with the U.S. Constitution.”<sup>24</sup>

In Singer’s view, patents are not needed to encourage development of new methods.<sup>25</sup> He believes the rapid advancement of medicine from World War II to the late 1970s in the absence of medical method patents “undermines the central claims that economic incentive is needed to induce innovation in the realm of medical procedures.”<sup>26</sup> One could argue that medicine would have advanced even more rapidly in the presence of medical method patents, thus improving health care. Also, it should be kept in mind that many scientific, engineering, and medical disciplines enjoyed exponential growth after World War II because the government funded them. Thus, funding and not patent protection was probably the most important driver of innovative activity. Furthermore, it is likely that many of the advances in medicine were product innovations, not procedure innovations. And patents were granted on products. Thus, Singer’s empirical argument is unsupported at best and specious at worst. Nevertheless, Singer believes that current patent

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<sup>22</sup> Free Exchange, p.4.

<sup>23</sup> Free Exchange, p. 14.

<sup>24</sup> Free Exchange, p. 14.

<sup>25</sup> Singer, J. Pamphlet: “Society Cannot Afford Surgical Method Patents and the Inhibition of the Free Exchange of Surgical Knowledge,” p. 4.

<sup>26</sup> Free Exchange, p. 13.



policy on surgical methods is not justified by its cost to society because society would have received the fruits of inventive activity without granting a patent monopoly.<sup>27</sup>

Singer delivers a strong argument against patenting medical methods that goes to the legal roots of the patent statutes, yet he supports the patenting of medical *products*. In his view, this is sensible because the cost of research and development for devices and pharmaceuticals is much greater than the cost of developing a technique. Patent protection is needed to encourage R&D investment. However, while he does acknowledge that some products may be cheap to develop and some techniques may be expensive to develop, he distinguishes what is and what is not patentable by generalizing the amount of R&D investment required for products as a class and methods as a class rather than by assessing required investment for a particular invention on a case-by-case basis, be it a product or a method:

“There are no costs to developing the frown incision. There were no costs to developing the chevron incision. It's done during the routine course of surgery on our patients. And we're getting paid for the surgery anyway. And it's done with instruments that we already have. There may be some cost in our time, in evaluating the outcomes, collecting the data, and presenting. But we do these presentations anyway as a matter of an ethical duty to share information freely, new advances with our colleagues at symposiums and journals. And there's no cost in marketing a procedure. There's no distribution cost. So I don't see any basis for patent protection of such procedures.”<sup>28</sup>

Although Singer opposes the patenting of medical methods and believes the patent system does not work in the medical culture, he believes the patent system works well for most inventions.<sup>29</sup>

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<sup>27</sup> Free Exchange, p. 14 and Singer, J. Pamphlet: “Society Cannot Afford Surgical Method Patents and the Inhibition of the Free Exchange of Surgical Knowledge,” p. 3.

<sup>28</sup> Singer interview, p. 6.



*Pallin v. Singer*

When Singer had learned that Pallin was patenting the chevron incision, he informed the Hitchcock Clinic. The Clinic consulted patent attorneys and then decided to wait to see if Pallin would enforce his patent. Singer says no one thought he would be sued because he had independently developed his frown incision.<sup>30</sup> But that assessment proved incorrect.

Singer believes Pallin brought suit against him because Pallin wanted an alternative source of income during his retirement years.<sup>31</sup> Although Pallin claims that he had applied for a patent because his report of the chevron incision was rejected, Singer believes Pallin had intended to obtain a patent even if his article were accepted. Singer says that Pallin applied for a patent after the first chevron incision and just days after being refused publication in the *Journal of Cataract and Refractive Surgery*. He finds Pallin's claims implausible because it takes time to assemble a patent application. Furthermore, Singer illustrates Pallin's proclivity toward ownership of the chevron incision by noting that the editor of the *Journal of Cataract and Refractive Surgery* told him that Pallin's article was rejected because Pallin refused to take a trademark symbol off the name of the incision.<sup>32</sup> The *Journal* did publish Pallin's article as a letter to the editor. Singer says he does not know how Pallin's work eventually got published in the 1991 Supplement to the *Journal of Cataract and Refractive Surgery* (Special Issue entitled "Small Incision Surgery: Wound Construction & Closure") because he thought Pallin's data needed some work.<sup>33</sup>

Pallin eventually published and obtained a patent, but why did he target Singer, who practiced ophthalmology on the other side of the country? Singer offers a few reasons:

"Well, I'm the physician who was credited with developing the frown incision, and his chevron incision is very similar to the frown incision in configuration. It was a V instead of a curve. He even claims a curve

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<sup>29</sup> Singer interview, p. 9.

<sup>30</sup> Singer interview, p. 10.

<sup>31</sup> Singer interview, p. 7.

<sup>32</sup> Singer interview, p. 7.

<sup>33</sup> In a letter to the *New York Times*, Charles Kelman said that Pallin's article was rejected partly because it was unoriginal (date of article not provided). See Lowes, R. "Are you stealing from other doctors? Medical procedure and method patents," *73 Medical Economics*, March 11, 1996, p. 195.





in his patent too. I think he felt that if he can force me to buy a license under his patent, it would make his patent more credible, lend validity to it and make it harder for other surgeons to fight it. And he felt probably that an ophthalmologist practicing in rural Vermont wouldn't have the resources to defend the costly patent litigation.”<sup>34</sup>

But it appears that Pallin and his attorneys did not know what they were up against. Singer's practice, The Hitchcock Associates of Randolph, is a small satellite clinic of the Hitchcock Clinic, a multi-specialty 800-physician group practice that comprises the clinical faculty of Dartmouth Medical School and constitutes a component of the Lahey-Hitchcock Clinic. Singer recalls Pallin's attorneys asking him numerous questions during deposition about the business structure of his practice for it seems they did not know that the defendants, Jack A. Singer, M.D. and the Hitchcock Associates of Randolph, were backed by the Hitchcock Clinic.<sup>35</sup> In Singer's view, they did not do their homework.

But perhaps the greater obstacles for Pallin lie not in the financial backing of what he and his attorneys apparently thought was a small unsupported clinic in rural Vermont but in the ethical stance taken by Singer and the Trustees of the Hitchcock Clinic. Singer saw the case as a crossroads to the future of medicine:

“Pallin's lawsuit against me for surgical method patent infringement is, I believe, the first of its kind and will establish case law with devastating consequences for all specialties of medicine, and therefore must be defeated. If Pallin were to have his way, scientific symposiums would become a stage for entrepreneurs to promote their techniques to an audience of prospective licensees rather than an

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<sup>34</sup> Singer interview, p. 5.

<sup>35</sup> Singer interview, p. 5.



opportunity for the practicing surgeon to be educated by academic leaders.”<sup>36</sup>

Singer drew a line in the sand and poised himself as the first line of defense:

“It would have been much easier to purchase Pallin’s license and let others worry about the problem . . . But from the beginning, I knew I had to fight this as a matter of principle.”<sup>37</sup>

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<sup>36</sup> Singer, J. Pamphlet: “Society Cannot Afford Surgical Method Patents and the Inhibition of the Free Exchange of Surgical Knowledge,” p. 4.

<sup>37</sup> Singer quoted in Shulman, S. “Cashing In on Medical Knowledge,” *Technology Review*, March/April 1998, p. 43.



## VII. Pallin's invention and patent

### Evolution of the Chevron Incision

#### *Inspiration*

Surgeons have always known that smaller incisions are probably better for the eye. Specifically, they have known that smaller incisions lead to less postoperative astigmatism. With Charles Kelman's invention of phacoemulsification in the 1970s, large incisions of up to 180 degrees (e.g., vonGraefe incision) were rendered unnecessary as phacoemulsification could be performed through scleral tunnels with three-millimeter incisions. According to Pallin, Kelman was able to reduce incision size to 1.5 millimeters.<sup>1</sup> As scleral tunnel incisions evolved, incisions were placed more posteriorly. Development of small incisions was deferred to ECCE with phacoemulsification.

However, with the introduction of rigid IOLs in the 1970s, fairly large incisions once again became the norm. Ophthalmologists once again explored ways to reduce incision size. In the middle 1980s, soft lens implants emerged. They could be folded and inserted through smaller incisions. According to Pallin, there was a public relations campaign by a lens implant manufacturer at that time which touted the insertion of a soft lens implant through an incision which required only one suture.<sup>2</sup> Pallin began to look for a way to make the incision self-sealing:

“About that time, many of us were using marginally smaller incisions with one suture, but that public relations and advertising campaign woke everybody up, I think. I knew that if you made it small enough there wouldn't be a big trick to make it self-sealing. The problem with it being small enough was that you still had to get a lens implant into the incision. So, I played with geometry – I used to make sketches and

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<sup>1</sup> Pallin interview, p. 2.

<sup>2</sup> Pallin interview, p. 2.



throw them away, did some research at the ASU [Arizona State University] West Side College library.”<sup>3</sup>

Pallin’s exploration was originally sparked by a statement made by Dr. Jim Gills in the late 1980s that it should be possible to create a watertight and sutureless incision for cataract surgery.<sup>4</sup>

### *Perspiration*

In his November 1990 letter to the editor of the *Journal of Cataract and Refractive Surgery* which reported his initial development of the chevron incision, Pallin stated that Dr. Gills’ declaration “has been achieved” with the work of Dr. Stephen Siepser who had created a sutureless radial incision coupled with a scleral tunnel through which a 3.5 millimeter foldable lens could be inserted.<sup>5</sup> Pallin also noted that Dr. Edward Kondrot had reported a self-sealing horizontal incision for foldable lenses and that Dr. Michael McFarland had reported a horizontal scleral tunnel incision with radial relaxing grooves which also admits foldable lenses.<sup>6</sup> It is interesting to note that Pallin did not report the sutureless or self-sealing trait of McFarland’s incision in spite of the fact that he cited an article on McFarland’s work in which the phrase “Sans Sutures” appears in the title. Perhaps he did not know. At the time of performing his first chevron incision (April 1990), Pallin says he had heard only of Siepser and McFarland doing sutureless incision work.

The incisions of others eliminated sutures, but they did not fulfill Pallin’s requirements for an incision. Pallin desired a small sutureless incision which would admit hard lenses, which are easier to

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<sup>3</sup> Pallin interview, p. 2.

<sup>4</sup> According to his November 1990 letter to the editor of the *Journal of Cataract and Refractive Surgery*, Pallin states that Gills made the statement “several years ago.” (See “Chevron Incision for Cataract Surgery,” 16: 779-81). However, a court document signed by Pallin in December 1993 (Plaintiff’s Supplemental Answer to Defendant’s Interrogatory No. 10) suggests that Pallin heard the statement of “Dr. Gill” (likely to be “Gills” misspelled) in 1988 or 1989 at a meeting of the Outpatient Ophthalmic Surgery Society.

<sup>5</sup> Pallin cites an article on Siepser’s work in the body of his letter: “Radial Incision Helps Reduce Astigmatic Forces,” *Ocular Surgery News*, March 15, 1990, p. 1.

<sup>6</sup> Pallin cites articles on Kondrot’s and McFarland’s work in the body of his letter: “Self-Sealing Tunnel Incision Facilitates Patient Recovery,” *Ophthalmology Times*, June 15, 1990, p. 1 (Kondrot), and “Surgeon Undertakes Phaco, Foldable IOL Series Sans Sutures,” *Ocular Surgery News*, March 1, 1990, p. 1 (McFarland).





control during insertion, and would therefore circumvent the problems of anterior capsulotomy tearing and enlargement caused by “semiexplosive unfolding” of soft lens implants. Furthermore, he wanted an incision that could be performed with current instrumentation, easily taught, and used reliably in virtually all clinical cases.<sup>7</sup> Later, Pallin included optimal instrument range of motion among his requirements.<sup>8</sup> Although Pallin thought Siepser’s “radial T” incision was “brilliant,” he thought it was dangerous and difficult to teach.<sup>9</sup> He considered the length of incision required to admit a 5 x 6 millimeter lens to be “excessively long.” In Pallin’s view, the “radial T” was dangerous because it required undermining the scleral tunnel to admit lenses. This increased the risk of hemorrhage because the surgeon had to work over the ciliary body. Pallin cited lack of adoption in the field as proof of the limitations of Siepser’s incision. Pallin considered using radial relaxing incisions at either end of the horizontal scleral tunnel, as proposed by McFarland, but discovered that with hard lens insertion the incision did not self-seal. Pallin considered other configurations and finally discovered the chevron:

“The chevron-shaped incision was a geometric shape which finally allowed me to fashion a scleral tunnel larger than the superficial episcleral incision, and additionally permitted the insertion of a 5 x 6 mm biconvex rigid lens into the anterior segment. Because of its shape, the chevron provides easy access to the scleral tunnel during the initial lamellar scleral dissection and also for the insertion of the implant device.”<sup>10</sup>

### *Invention*

The incision that resulted was at half scleral thickness and had an apex pointing inferiorly and located two millimeters posterior to the limbus at the 12 o’clock position (See Figure 1). Each lateral arm

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<sup>7</sup> S. Pallin, “Chevron Incision for Cataract Surgery,” p. 780.

<sup>8</sup> S. Pallin, “Chevron sutureless closure: A preliminary report,” *Journal of Cataract and Refractive Surgery*, 17: 706-9. Supplement 1991, p. 706.

<sup>9</sup> Pallin interview, p. 3.

<sup>10</sup> S. Pallin, “Chevron Incision for Cataract Surgery,” p. 780.



of about 2.5 mm in length defined an obtuse angle with a chord length of 3.5 mm externally and 4.0 mm internally (in the scleral tunnel). Furthermore, stretching of the incision facilitated insertion of a 5 mm lens.<sup>11</sup>

In his article in the 1991 Supplement to the *Journal of Cataract and Refractive Surgery*, Pallin reported different measurements and offered more detail into the mechanism of his incision and how his incision differed from the incisions of others. The apex of the V was now 1-2 mm posterior to limbus. The length of each arm was less than 2 mm. The angle created by the arms of the V ranged from 110 to 170 degrees. The chord length was less than 4 mm, but the width of the scleral tunnel was greater than 4 mm at the limbus. Pallin noted that the “variations in the angle and the distance of the apex from the limbus is influenced by the placement of the incision to avoid prominent blood vessels.”<sup>12</sup> Regarding how his incision differed, Pallin wrote:

“The chevron incision differs from classic cataract incisions in that the direction of the extremities is away from the limbus rather than parallel to the limbus or straight. The chevron entry into the anterior chamber differs from other sutureless closures in that the entrance is at the limbus rather than forward in clear cornea as described by McFarland . . .”<sup>13</sup> (Author’s note: See Figure on Incision Shapes for “Ophthalmology for *Pallin v. Singer*”)

But Pallin’s most interesting statements concerned his theory of the mechanism of self-sealing as he explicitly discarded the more popular corneal tissue<sup>14</sup> (flap, lip, valve, seal) hypothesis (See Figure 2):

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<sup>11</sup> Pallin cautions that the incision must be half scleral thickness because a superficial incision leads to difficulty in performing uniform dissection with durable flap tissue and a deeper incision may lead to unroofing the ciliary body with concomitant bleeding or poor structural integrity of the wound.

<sup>12</sup> S. Pallin, “Chevron sutureless closure: A preliminary report,” *Journal of Cataract and Refractive Surgery*, 17: 706-9. Supplement 1991, p. 707.

<sup>13</sup> S. Pallin, “Chevron sutureless closure: A preliminary report,” *Journal of Cataract and Refractive Surgery*, 17: 706-9. Supplement 1991, p. 707.



“There is no corneal flap mechanism to explain the closure of this tunnel. It is effectively self sealing, however, and the explanation appears to lie in the relationship between the geometry of the incision and the physical formula that describes the tension in the wall of a sphere as it relates to the pressure of the fluid contents of that sphere ( $\sigma = PR/4$  where P is pressure and R is radius), while sigma ( $\sigma$ ) is tension in the sphere wall). As pressure rises in the globe there is a tendency for any two points on the surface of the globe to move away from each other. The extremities of the incision then move away from each other as pressure rises. The shape of the chevron entry to the scleral tunnel tends to change from an obtuse V to a straight line as intraocular pressure (IOP) increases. The surgeon observes tensioning of the lips of the wound with a tendency to closure rather than a wound gape. As the IOP rises, it reaches a point at which the pressure exceeds the atmospheric pressure inside the scleral tunnel and the tunnel collapses. This, coupled with the tendency for wound edges to close with increasing tension in the sclera, results in a seal of the cataract wound.”<sup>15</sup>

Pallin describes the tunnel as “effectively” self-sealing without defining what is meant by “effectively.” The issue of describing the extent of self-sealing would be raised repeatedly by the defense in *Pallin v. Singer*. In deposition in 1994, Pallin offered an empirical explanation for self-sealing (See Figure 3 along with text below):

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<sup>14</sup> The corneal tissue is also referred to as a corneal flap, corneal lip, corneal valve, and corneal seal.

<sup>15</sup> S. Pallin, “Chevron sutureless closure: A preliminary report,” *Journal of Cataract and Refractive Surgery*, 17: 706-9. Supplement 1991, p. 707.



“there is a concept in which one understands that the length of the tunnel, the scleral tunnel, determines whether or not inflation pressure in the globe will cause the wound to close. If the tunnel is very wide but short in length, in anterior length, posterior length, back to front length, tendency to leak is high. Tendency to seal is low. If the tunnel is long in the linear sense but narrow, the tendency to seal is high and the tendency to leak is low. So that if you’re asking me if one makes five different incisions where at one point the incision is a given distance from the limbus, what happens with five different shapes, I will tell you that the shape that curves towards the limbus tends most to leak and least to seal. The shape which looks like a straight line tends moderately to leak and moderately to seal. And the shape where it curves or angles away from the limbus will tend least to leak and most to seal.”<sup>16</sup>

The chevron fulfilled Pallin’s requirements and offered a number of other benefits. He enjoyed the suture-free aspect of the incision, and his findings suggested negligible postoperative astigmatism. By the time he submitted his 1991 Supplement article, Pallin had used the chevron on over 700 eyes. He was able to use a wide range of lenses from 5 x 6 lenses to one 7 mm lens. He found no correlation between implant size and either self-sealing of the wound or iatrogenic astigmatism. He noted, however, that seven eyes required a suture because the wounds did not self-seal. Pallin wrote that the chevron incision offered the benefits of time reduction (noting that 30% of operation time is spent placing and tying sutures), fewer complications because the eye experiences less time exposed to surgical manipulation and hypotony, surgeon satisfaction, minimized astigmatism (stating that others had also reported favorable results with self-sealing incisions, citing Kondrot and McFarland articles), and intraoperative safety, for which Pallin offered the following anecdote:

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<sup>16</sup> 6/13/94 Deposition of Samuel Pallin, pp. 56-7. Cited in Defendants’ Memorandum Addressing Markman





“An anecdotal example of the reassurance provided by this safety factor is the obese diabetic patient I encountered early in this patient series. After phacoemulsification and aspiration of lens material, the patient developed acute congestive heart failure and became extremely agitated. She could not be safely restrained to continue the procedure. She was transferred by ambulance to a local hospital. One week later, after stabilization, she returned for an elective IOL implantation under local anesthesia. The wound had self sealed. There was no opportunity to place sutures and it is likely that this would have been a catastrophic event in the absence of the self-sealing incision.”<sup>17</sup>

### The Patent Application Process

#### *Rejection and Submission*

In Pallin’s view, the only published account of a sutureless incision at the time of his first chevron incision was Siepser’s radial T. According to Pallin, McFarland did not describe his incision and did not publish it in a peer-reviewed journal, but McFarland was credited with inventing the sutureless incision. In pursuit of credit for his work, Pallin submitted a paper to the *Journal of Cataract and Refractive Surgery* the day after he performed his first chevron incision (April 17, 1990). But suspecting that he was being stonewalled, he applied for a U.S. patent:

“Within a week or two, I had my secretary start to call to see if the paper was creating some excitement. And very quickly got the idea that I was being stonewalled and that nobody was going to publish that paper, even before I got a formal answer which took months. There



was a lot of work going on. It was clear to me that if I wanted to get credit for it, you had to get published or do something else. So very quickly I applied for a patent. A few weeks or a month or two later.”<sup>18</sup>

Pallin believed the editorial staff was elitist and unprepared to hear something from him. He also believed that industry and physician interest in soft lens implants made for an environment unreceptive to an incision that could admit soft and hard lenses. While Pallin was applying for a patent, he engaged in an ongoing conversation with the ASCRS editorial staff, which he believes reluctantly accepted his article for publication in 1991 because he “was making a pretty big stir.”

Pallin says he does not remember the details of his interactions with the editorial staff of the *Journal of Cataract and Refractive Surgery*, but he remembers receiving a “rude and inappropriate” response to his initial calls several months after his original submission:

“It was like “yesterday’s news” was I think a quote. It infuriated me.

Then I decided I was certainly going to go through with the patent if I could get it. And I did.”<sup>19</sup>

Harry Wolin, Pallin’s patent attorney, submitted Pallin’s patent application on June 28, 1990. It consisted of twelve pages of specifications, two pages of drawings, a combined declaration and power of attorney, and a payment of \$257.<sup>20</sup> Pallin’s application was assigned to John Yasko and William Lewis, primary and assistant patent examiners respectively.

In submitting his patent application, Pallin signed off on a number of truth statements that were cited by the defense in *Pallin v. Singer* when it accused him of inequitable conduct at the Patent and

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<sup>17</sup> Pallin concludes his article by writing that more evaluation is needed but the initial results are encouraging. S. Pallin, “Chevron sutureless closure: A preliminary report,” *Journal of Cataract and Refractive Surgery*, 17: 706-9. Supplement 1991, p. 708-9.

<sup>18</sup> Pallin interview, p. 3.

<sup>19</sup> Pallin interview, p. 4.

<sup>20</sup> Pallin’s patent application (Serial #544984) fee consisted of the basic fee for a small entity of \$185, fee for nine additional claims (beyond 20) of \$54, and fee for three independent claims (beyond 3) of \$18.



Trademark Office (PTO) for not disclosing the work of Siepser and McFarland. The most critical statements read:

“I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, § 1.56 (a).”<sup>21</sup>

“I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.”<sup>22</sup>

#### *Revision and Review*

Pallin’s patent appears to have been issued relatively easily with only a few intervening administrative<sup>23</sup> and substantive issues. The quality of the patent examination was probably average at best. On June 25, 1991, almost a year after Pallin filed his application for a “Self-Sealing Episcleral Incision,” the PTO rejected and listed as pending all 29 claims in Pallin’s application because they were directed toward non-statutory subject matter and they did not specifically designate the subject matter which constituted the invention.<sup>24</sup> Pallin’s claims, as written, were directed toward parts of the human

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<sup>21</sup> “Combined Declaration and Power of Attorney in Original Application,” p. 1.

<sup>22</sup> “Combined Declaration and Power of Attorney in Original Application,” p. 2.

<sup>23</sup> Pallin faced only two administrative issues. At one point, the PTO asked for payment of additional fees because it classified him as a large entity. However, the situation was rectified with Pallin’s declaration that he qualified as an independent inventor. As the examination process continued, Wolin forwarded the appropriate fees.

<sup>24</sup> 6/25/91 communication from William Lewis to Harry Wolin, p. 2 in Pallin patent file.



body. The patent application text claimed “an episcleral incision” rather than a method of making such an incision. On August 6, Wolin submitted revised claims under the amended title “*Method of Making a Self-Sealing Episcleral Incision*” (emphasis mine) to the PTO.<sup>25</sup> Lewis, the assistant examiner, also deemed the drawings in the application “so informal that they cannot be corrected” and requested new drawings.<sup>26</sup> Finally, Lewis cited four U.S. patents for Pallin’s review as possible prior art.

Pallin had reviewed the patents cited by Lewis and believed that none of them affected the patentability of his invention.<sup>27</sup> All four cited patents,<sup>28</sup> which had been issued in the 1980s, were originally examined and approved by Ronald Frinks, a primary examiner with experience in reviewing ophthalmology inventions. None of the inventions represented by the four patents constitutes prior art, and none of them would appear to render the Pallin invention obvious. Thus, the four patents did not stand to affect the patentability of Pallin’s incision method.<sup>29</sup>

While Pallin was reviewing the four patents, Lewis was conducting the substantive patent examination and review, which was probably no better than average. On June 12, 1991, Lewis searched the PTO archives for potentially relevant literature.<sup>30</sup> Lewis performed an automated patent search on August 27.<sup>31</sup> The search yielded five patents, but there is no record to suggest that these were referred to Pallin or Wolin for review. Lewis consulted Ronald Frinks on September 5, and checked interference (e.g. other patent applications) on September 6. It is noteworthy that the current medical or ophthalmology

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<sup>25</sup> The accompanying remarks admitted that the previously submitted claims claimed parts of the eye and specified that the claimed subject matter was a method of making an incision, not an incision itself.

<sup>26</sup> Lewis sent Wolin a “Notice of Patent Drawings Objection” which cited poor paper, numerals, lines, and figures. The original set of drawings were hand-drawn on lined paper with handwritten text.

<sup>27</sup> 8/6/91 Amendment letter from Wolin to PTO, p. 6.

<sup>28</sup> Patent # 4,607,617 “Apparatus and Method for Improving Eyesight” granted on 8/26/86 to David Choyce; Patent # 4,706,666 “Positioning Implement for Intraocular Lens” granted on 11/17/87 to John Sheets; Patent # 4,619,657 “Flexible Intraocular Lens Holder” granted on 10/28/86 to Richard Keates; and Patent # 4,702,244 “Surgical Device for Implantation of a Deformable Intraocular Lens” granted on 10/27/87 to Thomas Mazzocco.

<sup>29</sup> Only one of the four patents claims an incision method, but it is a method of making an incision into cornea, not sclera, for the purpose of implanting a lens between the layers of the cornea.<sup>29</sup> The second patent for a positioning implement claims only a product, unlike the Pallin application which claims a method. The third patent is primarily a product patent but also has a few claims for a method of implanting an intraocular lens holder. The fourth patent is also primarily a product patent which has a few claims for a method of using a surgical device for implantation of a deformable ocular lens.

<sup>30</sup> Search Notes in Pallin patent file.

<sup>31</sup> He used the following keywords in various combinations of Boolean logic: sclera, limbus, (incision or cut), posterior, and lense [misspelled attempt at “lens”].





literature was not searched. At the time of Pallin's patent application, searching electronic databases of medical literature was not common procedure, as it is now.

### *Issuance*

Yasko and Lewis accepted Pallin's revised claims on September 11, 1991 and Wolin subsequently submitted new drawings (produced with a computer graphics program) on September 27. On October 14, Wolin paid a \$525 issuance fee and ordered ten advance copies of the patent, which was formally issued on January 14, 1992.

### U.S. Patent #5,080,111

The five pages, six text columns, and twenty-nine claims of Patent # 5,080,111 caused a storm in the ophthalmology community when Pallin enforced them against a peer. The purpose of this section is to provide an overview of the patent and to highlight key sections and ideas which sparked debate and informed the Court (See Table – Contentious Patent Text). The abstract of Pallin's patent reads:

“A substantially self-sealing episcleral incision having an approximate central point 1.5 to 3.0 millimeters posterior to the limbus. Portions of the incision extending from the approximate central point extend laterally away from the curvature of the limbus. The configuration of the self-sealing incision allows the incision to seal as the eye is inflated following surgery and therefore requires no sutures for sealing. Accordingly, the probability of astigmatism is eliminated or greatly reduced and the reliance on sutures is eliminated.”<sup>32</sup>

### *Background of invention*



In his patent, Pallin provides a rationale for developing the chevron incision. He describes that state-of-the-art in cataract microsurgery and artificial lens implantation and highlights some of the problems encountered in surgical practice. He notes that the standard incision is “either linear or approximately follows the curvature of the limbus,” and that suture-induced astigmatism is a common problem in cataract surgery.<sup>33</sup> Though suturing a scleral incision positioned farther from the limbus, as in scleral tunnel surgery, results in less suture induced astigmatism, that patent states, “it would be highly beneficial to have an episcleral incision that may be employed with scleral tunnel microsurgery that is substantially self-sealing, will admit solid or folded lens implants and greatly reduces or eliminates the probability of astigmatism.”<sup>34</sup>

### *The Invention*

Pallin believes his incision achieves the aims of self-sealing, greatly reducing or eliminating astigmatism, forgoing reliance on sutures, reducing incisional stress with lens implantation, allowing the insertion of solid and folded implants of various sizes, and offering variable chord length.<sup>35</sup> The patent says the self-sealing nature of the incision will render surgical emergencies such as hemorrhages controllable. The incision configurations allow stretching without tearing. Variable cord length allows for insertion of solid or folded lens implants. Specifically, “[f]or example, a solid ovoid biconvex lens implant having dimensions of 5 millimeters by 6 millimeters may be successfully inserted into an incision...having a chord length of 3.5 millimeters without tearing the incision.”<sup>36</sup> The defense in *Pallin v. Singer* would later use this sentence to show the resemblance between Pallin’s incision and that of another ophthalmologist.

The patent describes in detail the processes of making an incision, capsulorhexis, phacoemulsification, and IOL implantation with reference to simplified anatomical diagrams of the eye.

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<sup>32</sup> U.S. Patent #5,080,111 “Method of Making a Self-Sealing Episcleral Incision” granted on 1/14/92 to Samuel L. Pallin.

<sup>33</sup> Furthermore, he identifies a number of suture complications, including irritation of the eye, suture abscesses, suture extrusion, foreign body reaction, and suture breakage.

<sup>34</sup> U.S. Patent #5,080,111, col. 1-2.

<sup>35</sup> U.S. Patent #5,080,111, col. 2.

<sup>36</sup> U.S. Patent #5,080,111, col. 4, lines 37-41.



Though no mention of Singer's frown incision is made, Figure 4 of the patent document clearly depicts a frown-shaped incision (See Figure 4). Figures 3 and 4 of the patent document represent a chevron-shaped<sup>37</sup> and a curvilinear incision respectively. The patent states a number of preferences and requirements for the incisions depicted in Figures 3 and 4. An angle of 100 to 160 degrees is preferred for the chevron-shaped incision, but an angle in the range of 80 to 175 is acceptable. For the chevron-shaped incision, the preferred location of the apex is 2 millimeters posterior to the limbus. For the curvilinear incision, although the preferred location of the central point of the incision is 2 millimeters posterior to the limbus, distances in the range 1.5-3 millimeters are acceptable. The inclusion of a curvilinear analog of the strictly chevron-shaped incision would figure prominently in *Pallin v. Singer*.

Regarding the mechanism of incision sealing, which also figured prominently in *Pallin v. Singer*, the patent states that when the eye is inflated after surgery, the force vectors acting on the incisions (referring to the chevron-shaped and curvilinear incisions in Figures 3 and 4 of the patent document) induce closure of the scleral tunnel yielding a water-tight and sutureless incision wound.<sup>38</sup> Other ophthalmologists believed corneal tissue (i.e., corneal flap, lip, valve, seal) caused self-sealing.

But perhaps one of the thorniest issues raised in the case is embodied by the following:

“Further, even larger lens implants of up to 6 millimeters in diameter may be inserted through larger incisions. . . .although a single suture may occasionally be required for complete sealing.”<sup>39</sup>

Pallin claims to have invented a sutureless incision method, but his patent appears to allow the use of a suture. Pallin prefaced the listing of his patent claims with the following:

“While specific embodiments of the invention have been shown and described, further modifications and improvements will occur to those

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<sup>37</sup> The words “chevron” and “frown” are never used in Pallin's patent.

<sup>38</sup> U.S. Patent #5,080,111, col. 4, lines 6-16.

<sup>39</sup> U.S. Patent #5,080,111, col. 4, lines 41-45.



skilled in the art. It is desired that it be understood, therefore, that this invention is not limited to the particular forms shown and it is intended in appended claims to cover all modifications which do not depart from spirit and scope of this invention.”<sup>40</sup>

Pallin enforced claims 1, 7, 22, and 28 against Singer (See Table – Contentious Patent Text). Of the 29 claims in the patent, these were the only claims at issue in *Pallin v. Singer*. Many claims in Pallin’s patent are redundant and collapsible into one another, perhaps in order to close legal loopholes. Thus, individual components of the invention and combinations of the same components are claimed.<sup>41</sup> Claims 1 and 7 cover the basic invention for chevron-shaped and curvilinear forms. Although the patent contains claims on making a scleral tunnel for the chevron-shaped and curvilinear incision forms, only the one pertaining to the curvilinear form is enforced. This makes sense because Singer used a curvilinear incision with a scleral tunnel. He did not use a chevron-shaped incision, although a chevron at a wide angle may resemble a curvilinear form, as discussed later in *Pallin v. Singer*.

### *Other Seeds of Contention*

The Pallin patent contained other seeds of contention. Although the abstract (preamble) mentions suturelessness as the essence of the invention and Pallin claims a sutureless incision, his patent teaches that a suture may be needed for complete sealing of a wound made for large diameter lenses. Early in the course of *Pallin v. Singer*, Pallin claimed that his patent covers the straight line incisions of McFarland. However, later in the case, Pallin claimed that his patent does not cover straight lines.<sup>42</sup> As the case progressed, the nature of Pallin’s interpretation as it applied to anticipation and infringement would be hotly disputed. Pallin believed the mechanism of self-sealing lay in force vectors on the incision during

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<sup>40</sup> U.S. Patent #5,080,111, col. 4.

<sup>41</sup> For instance, claim 2 is an extension of claim 1, and claim 3 is an extension of claim 2. Claim 2 reads: “The method of claim 1 further including making an incision having a depth in the range of 25 to 75 percent of the thickness of the sclera.” Claim 3 reads: “The method of claim 2 further including making an incision having a depth of approximately 50 percent of the thickness of the sclera.”

<sup>42</sup> See claims 8, 9, and 19 and col. 3, lines 47-49. Pallin’s patent does refer to the arms of the chevron-shaped incision as “substantially linear portions.”





re-inflation of the eye. Singer would later challenge this in court by marshaling a crew of expert witnesses. Curiously, the definition of the limbus, a commonly used anatomical landmark, would also become an issue.

Items believed to be omitted from Pallin's patent also formed the basis for arguments against Pallin in *Pallin v. Singer*. The defense would claim that Pallin's patent does not limit the type of lens used. In fact, Pallin sought an incision that would admit foldable and hard lenses. The defense would also claim that Pallin's patent did not expound on required dimensions of the scleral tunnel, specifically the length to width ratio. Although the patent describes a tunnel that is wider at its entry into the anterior chamber of the eye than at the incision site, the patent does not address the length of the tunnel.<sup>43</sup>

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<sup>43</sup> The invention description states that it "should be understood that scleral tunnel...will probably have to be wider than the cord length of incision...where it encounters anterior chamber." This idea is stated more definitively in claim 18, 21, and 29. All of the claims omit the word "probably." U.S. Patent #5,080,111, col. 4. Pallin had stated in deposition in 1994 that the length to width ratio of the tunnel determines wound closure, but the patent does not discuss this ratio.



## VIII. First phase of judicial proceedings

As *Pallin v. Singer* gained momentum, the legal maneuvering, vitriolic attacks, and vigorous defensive efforts intensified. As the development of the sutureless incision and the nature of invention in ophthalmology came to light, each side shifted its arguments to accommodate new facts while maintaining its position. Although infringement was the core legal issue, both the plaintiff and defense tried to overcome the opponent in other venues of legal and ethical debate, such as issues over the validity of Pallin's patent, alleged flaws in the patent application process, the relative safety of incision techniques, the inventor's intentions in inventing, and the credibility of witnesses (See Figure 1). At the center of the public debate over *Pallin v. Singer* was the issue of the ethics of patenting medical methods. However, the court did not have to address this issue or assess the legality of patenting medical methods. Thus, the case possessed few mentions of or allusions to the ethical issue. As in any patent infringement suit, there was a constant effort to define the invention and to compare it to the infringing work. In the course of *Pallin v. Singer*, the conception of what the chevron incision is constantly changed, as did the understanding of who invented what and when (See Timeline 1A).

The first phase of the case was a procedural tug-of-war interrupted by a bombshell accusation that Pallin had engaged in fraudulent conduct. The plaintiff made many attempts to settle the case but failed.

### Attempting to Stack the Cards in Its Favor

With no royalty settlement and disagreement over procedural issues, the judicial process resumed when the plaintiff filed a Motion to Compel on April 28, 1994.<sup>1</sup> The Motion requested that the Court compel Singer to answer relevant questions that he had "unjustifiably refused to answer" at his deposition in November 1993 and to answer questions about his position on patent validity, infringement, and solicitation of defense funds. It also asked the Court to compel the defense to identify its expert witnesses, to limit its number of experts to one, and to award expenses for this motion to the plaintiff. Thus, the

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<sup>1</sup> Motion to Compel (filed 4/28/94) in court documents for *Pallin vs. Singer*, No. 5:93-CV-202 (D. Vt. filed July 6, 1993). Court documents stored in National Archives and Records Administration facility in Waltham, MA.



plaintiff set about maneuvering to stack the cards in its favor even though many of its demands were off base.

The first issue stems from plaintiff lawyer White's futile efforts during deposition to inquire about a recent statement Singer had apparently made to the press to the effect that his frown incision had predated Pallin's patent application. While White was trying to ascertain when Singer had conceived and developed his incision, Singer's attorney instructed him not to answer questions that dealt with time frame, manner of conception, and technical details of his incision because the opposing parties had not yet agreed on a way to handle such information.<sup>2</sup>

One of the risks involved in divulging information about the development timeline of an invention without concurrent disclosure of similar information from the other party is that the other party could reinterpret or modify its chronology to strengthen its patent position. However, the plaintiff viewed Singer's refusal to answer questions regarding timeline as legally improper. In the plaintiff's view, because the defendants had claimed Pallin's patent was invalid, and therefore had questioned patent enforceability, they had to disclose all prior art supporting their assertions.<sup>3</sup> However, Singer's attorney, George Neuner, later pointed out that Singer did not answer "certain questions posed during his deposition" because Pallin had previously refused to answer similar questions.<sup>4</sup> The defense wrote that counsel on both sides had agreed off the record at Singer's deposition that, at an agreed upon date, Pallin and Singer would simultaneously provide dates of invention.<sup>5</sup>

The second issue in the Motion to Compel concerned the solicitation of funds for Singer's defense. Pallin's attorney believed he had a right to question Singer and Collins, CEO of the Hitchcock

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<sup>2</sup> Deposition of Jack Singer, Vol. 1 (taken 11/5/93), pp. 27, 42 in Motion to Compel. Singer's deposition transcript exhibits White's foiled attempts to ascertain a chronology of events: Q: What led you to eliminate the use of a suture in most of the cases? // A: The internal corneal valve incision that I had learned became part of the frowning, became part of my cataract procedure and wound construction procedure which then made it safe to eliminate the suture. // Mr. White: Can I ask him about when he learned about a corneal valve incision? // Mr. Neuner: Timewise, I am going to instruct him not to answer that right now because of, you know, it comes into this whole thing of time. // Mr. White: Because you think I'm sneaking up on the time line? // Mr. Neuner: Well, it's insidious about how that happens so I would prefer not to.

<sup>3</sup> Motion to Compel, p. 5.

<sup>4</sup> 3/11/94 Letter from Neuner to White in response to White's 3/10/94 Notice of Deposition to Singer and Collins.



Clinic, on this issue because they had expressed thoughts in their letter to ophthalmologists which commented on the merits of the court case.<sup>6</sup> White could then test his belief that Singer opposed the Pallin patent because he opposed all medical method patents and not Pallin's patent alone. However, Neuner responded that Collins had no personal knowledge of infringement and that the Singer Defense Fund was not an issue in the current litigation.<sup>7</sup>

The arena of witnesses served as another forum for disagreement and legal maneuvering. In a letter dated February 16, 1994, White had informed Neuner that Pallin would serve as his own expert witness and would use Dr. Paul Kainen for geometry and mathematics of the incision.<sup>8</sup> In May, defense counsel reported difficulty in questioning Pallin and Kainen and complained that Kainen was ultimately dropped from the list of witnesses. Pallin's attorneys did not allow defense counsel to question Pallin because he had already been questioned on January 7 and 8. However, the defense countered that Pallin needed to be questioned as an expert witness; his previous deposition was as a fact witness. As a fact witness, Pallin is a patentholder who believes his patent has been infringed. In deposition, the patentholder would be probed about dates of invention, manner of conception, and technical details of the invention, including but not limited to structure, function, and mechanism. However, an expert witness serves to comment on, among other things, the technical details of the invention, the level of skill of the average practitioner in the field, and the developmental history and the state of the art in the field at the time of invention. On April 27, the defense moved to compel Dr. Pallin to sit for a deposition as an expert witness.<sup>9</sup> The plaintiff filed opposition two weeks later stating that the "issues relevant to Dr. Pallin's

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<sup>5</sup> The defense states that such practice is common in patent suits. Defendants' Opposition to Plaintiff's Motion to Compel (filed 5/6/94), p. 2.

<sup>6</sup> White says that he tried to depose Singer and Collins on March 10 but to no avail. 4/26/94 affidavit of John White.

<sup>7</sup> 3/14/94 Letter from Neuner to White. Neuner stated that Singer had been available for deposition on April 14 in defense counsel's office in Boston, but the plaintiff wanted to take deposition on March 28. Neuner also pointed out that the defense had accommodated Pallin by taking his deposition on a Saturday in Pallin's home city of Phoenix. He added that the plaintiff has not paid the plane fare in advance as was previously agreed to.

<sup>8</sup> 2/16/94 Letter from White to Neuner in Motion to Compel (Exhibit L).

<sup>9</sup> This motion also moved to extend the time of the discovery period. This document is not available in court records. However, the plaintiff's reply is available.





testimony have been fully developed,”<sup>10</sup> and that the defense was only engaging in a strategy of delay because it had been unable to make a case for invalidating Pallin’s patent.

White complained that the defense had not yet identified expert witnesses even though the deadline<sup>11</sup> for identifying witnesses had passed. However, in an April 1 letter to White, Neuner lists three possible witnesses (Drs. Paul Ernest, Howard Fine, and Richard Kratz) and says that the defense only has to identify its expert witnesses 30 days after receipt of deposition transcripts from the plaintiff’s expert witnesses.<sup>12</sup>

White’s most curious request is to compel the defense to limit its expert testimony to one witness:

“Given the small amount at stake, the few issues in contention, and the expressed intent of the plaintiff to use a single expert, defendants should likewise be limited.”<sup>13</sup>

The defense countered that limiting it to a single expert witness is “both unsupported by case law, and premature.”<sup>14</sup> However, the defense also reassured the plaintiff and the court that it did not intend to duplicate testimony as each expert witness would speak on a different technical area.

The “small amount at stake” was \$5,000, the price offered to the defense to purchase a lifetime license. The defense, however, saw much more than a “small amount at stake”:

“Plaintiff apparently argues that, because he has now limited his number of experts to one, Defendants should be required to do likewise. Of course, that is nonsensical. Nor does Plaintiff’s assertion that there is a ‘small amount at stake’ here, with ‘few issues in contention’ make any sense. In Defendants’ view, what is at stake is a

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<sup>10</sup> Plaintiff’s Opposition to Defendants’ Motion to Compel Enforcement of the Joint Discovery Order and Request for Extension of the Discovery Period (filed 5/10/94), p. 3.

<sup>11</sup> As specified in the joint discovery schedule.

<sup>12</sup> 5/2/94 Letter from Neuner to White in Motion to Compel (Exhibit M).

<sup>13</sup> Motion to Compel, p. 10.



very important ethical principle – whether one doctor should be allowed to claim exclusive rights to a surgical technique. The number of issues in contention is the same as in virtually every patent litigation – invalidity, noninfringement, and unenforceability. Yet, Plaintiff fails to cite a single case that supports his attempt to limit the number of expert witnesses.”<sup>15</sup>

The plaintiff once again displayed an eagerness to settle and was so eager that he was willing to attempt to limit the number of witnesses. Perhaps, the plaintiff wanted to move on to other defendants, to avoid having to pay the expenses of more witnesses,<sup>16</sup> or simply to hinder the defense in any way possible.

#### Charging Inequitable Conduct

The defense accused Pallin of inequitable conduct at the U.S. Patent and Trademark Office during his patent application process. The defense moved to add to its previous legal brief the paragraph below, which if true, would be very damaging:

“On information and belief, U.S. Patent No. 5,080,111 is unenforceable by reason of Plaintiff’s inequitable conduct in wrongfully failing to disclose to the U.S. Patent and Trademark Office, during prosecution of the application that issued as the patent in suit, material prior art of which he was aware.”<sup>17</sup>

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<sup>14</sup> Defendants’ Opposition to Plaintiff’s Motion to Compel (filed 5/6/94), p. 8.

<sup>15</sup> Defendants’ Opposition to Plaintiff’s Motion to Compel (filed 5/6/94), p. 8-9.

<sup>16</sup> In interview, in 1998, Pallin said that he could not afford to hire witnesses. Pallin interview, p. 18.

<sup>17</sup> Memorandum of Points and Authorities in Support of the Motion of Each Defendant for Leave to Amend (filed 4/28/94).



If it could be shown that Pallin engaged in inequitable conduct, his patent would be rendered unenforceable even if it was ultimately deemed valid by the court. Thus, Pallin stood to lose not only the lawsuit but also the patent itself.

The defense charged that Pallin knew of the sutureless surgery work of Dr. Robert McFarland and Dr. Stephen Siepser because he referred to it in his August 15, 1990 letter to the editor of *Ocular Surgery News*, and he apparently mentioned this work in his deposition. The defense strengthened its case by citing Dr. Richard MacKool, an expert for the defense, who stated in deposition that he had used a scleral incision that curved away from the limbus and had used a scleral tunnel in connection with cataract surgery as early as 1985-86. MacKool also said he used a suture until he learned of McFarland's work in the 1989-91 timeframe. The defense contended that the prior art of McFarland and Siepser was material because a reasonable examiner would consider it important in assessing patentability.

However, the defense proceeded from the premise that the work of Pallin and that of McFarland and Siepser were all in the same genre, methodologically. All yielded a similar or identical end result – a sutureless incision. But perhaps the methods employed and the technical context developed to yield each incision were different, or if they were the same, the defense did not expound on this. It might be like saying balloon angioplasty for removing plaques from cardiac vessels must be stated as prior art for assessing the patentability of a clot lysis drug, such as streptokinase, for clearing obstructed cardiac vessels. The two inventions employ different mechanisms to achieve the same result. The defense's contention may have been correct, but without explanation, it was irrelevant.

Pallin's August 15, 1990 letter to the editor in which he refers to the work of McFarland and Siepser does raise the suspicion of inequitable conduct, but a party must show clear and convincing evidence of such conduct, or in the view of the defense, must show clear and convincing contextual evidence from which wrongdoing can be inferred.<sup>18</sup> The defense contended that because Pallin trumpeted elimination of sutures as the key feature of his invention (quoting the preamble of his patent; see Table –

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<sup>18</sup> The plaintiff and defense appear to disagree on the legal standard for determining inequitable conduct in this case. The defense cites a recent case, *LaBounty Mfg. Inc. v. U.S. Int'l Trade Commission*, 22 U.S.P.Q.2d (Fed. Cir. 1992), which says, "direct proof of wrongful intent is rarely available, but may be inferred from clear and convincing evidence of the surrounding circumstances." (p. 1032) The plaintiff contends that wrongdoing cannot be inferred but must be shown by clear and convincing evidence.



Contentious Patent Text) and did not disclose the sutureless surgery work of McFarland and Siepser, he possessed wrongful intent.<sup>19</sup> But Pallin might have heard of the work of McFarland and Siepser after he had invented his incision, and he might have assumed he was still the first to invent a sutureless incision technique that also allowed improved instrument manipulation and visualization during surgery.

The defense's evidence did not support an accusation of inequitable conduct.<sup>20</sup> The only testimonial evidence the defense cited was one sentence where Pallin stated, "I think the first three people to do no-suture incisions were Siepser and McFarland and me."<sup>21</sup> Pallin made no mention of the chronological relationship of the work of the three ophthalmologists. And, Pallin's deposition was in January 1994, nearly two years after his patent had been formally issued. If in 1994 Pallin did not know of the chronology of sutureless incision development, he is unlikely to have known during the examination of his patent application, unless he was intentionally withholding knowledge of chronology. But the defense offered no proof for this.

On May 10, 1994, the plaintiff formally filed opposition to adding a charge of inequitable conduct.<sup>22</sup> The plaintiff believed the defense had been unable to accumulate evidence for patent invalidation in the discovery period which had ended on May 2 and therefore charged fraud in an effort to invalidate Pallin's patent. The plaintiff offered technical detail to distinguish Pallin's work from those of others and pointed out that the defense was focusing solely on the sutureless aspect of the Pallin invention and ignoring other aspects, such as the ability of the incision to admit solid or foldable lenses and to reduce or eliminate incision-induced astigmatism. The plaintiff stated that Dr. James Gills, another pioneering ophthalmologist, reported a self-sealing incision but after Pallin had filed his patent application (See Timeline 1B). Gills had reported incisions 3-4 mm behind the limbus, which is not the same location used by Pallin. Furthermore, the defense did not describe the efforts of Siepser and McFarland, how well known their efforts were, or if their efforts were even relevant to the Pallin invention. The plaintiff remarked that there was no evidence that the publication of the McFarland and Siepser work, which

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<sup>19</sup> Memorandum of Points and Authorities in Support of the Motion of Each Defendant for Leave to Amend (filed 4/28/94), p. 5.

<sup>20</sup> Plaintiff's Opposition to Defendants' Motion for Leave to Amend (filed 5/10/94).

<sup>21</sup> Pallin Deposition, p. 247.

<sup>22</sup> Technically, the defense added an affirmative defense of inequitable conduct.





occurred in the year before Pallin filed his application, even disclosed Pallin's invention. The plaintiff then addressed MacKool's testimony by claiming that MacKool's words "cited by the defendants show that all other efforts besides Pallin's were critically different in technique and size and that further adaptation of the idea, at a minimum, was necessary."<sup>23</sup>

Viewing the charge of inequitable conduct as a "smokescreen," the plaintiff wrote that the defense had not presented "even the slightest scintilla of evidence" regarding Pallin's intent. The plaintiff argued that inequitable conduct cannot be inferred but must be shown by clear and convincing evidence. In supporting a charge of inequitable conduct, the defense must prove, in addition to wrongful intent, that if the examiner had known about the "alleged" prior art, he would not have issued the patent. The plaintiff's opposition memorandum ended with an inflammatory statement: "this allegation is flung before the Court with hope that the Court will find bases for the allegation and bootstrap the defense into this case."<sup>24</sup>

#### Resetting the Cards from the Bench

On May 12, Judge Billings closed the first phase of the case by ruling on three pending motions.<sup>25</sup> Billings denied the Plaintiff's Motion to Compel stating that the information which Dr. Singer initially did not provide in deposition was provided later by letter to plaintiff's counsel. The judge also deemed the issue of litigation funding (Singer Defense Fund) irrelevant to the case at hand. In his Opinion and Order, Judge Billings explained that the joint discovery agreement requires the plaintiff to name his experts before the defense must identify its experts. Because the plaintiff did not comply with this aspect of the joint discovery schedule, the Court did not compel the defense to name its expert witnesses. Billings also refused to limit the number of witnesses the defense could call. The Court extended the discovery period to August 1 and ordered the plaintiff to make experts, including Pallin, available for deposition. Judge Billings added:

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<sup>23</sup> From 4/12/94 MacKool deposition. Only pp. 43-45 of the deposition are provided as an exhibit in the plaintiff's opposition memo, and nowhere in the three pages does MacKool mention the Pallin technique. What MacKool appears to be commenting on is suturelessness. MacKool thought suturelessness was amazing as a surgical technique because he did not think it could be done.

<sup>24</sup> Plaintiff's Opposition to Defendants' Motion for Leave to Amend (filed 5/10/94), pp. 16-18.



“Defendants, who admittedly have deposed Dr. Pallin as an actor, have yet to depose him in his role as an expert, a distinction with more substance than plaintiff’s counsel apparently recognizes.”<sup>26</sup>

Finally, Judge Billings allowed the defense to add the charge of inequitable conduct to support its claim that Pallin’s patent was invalid.

#### Conceding Ground to Soften a Resolute Defense

In the wake of Judge Billings’ ruling, the plaintiff made concessions in its settlement terms while vigorously holding to its position of patent infringement, and the defense remained noticeably reserved. The underpinnings for the position of the defense became remarkably clear. While the precise legal position of the plaintiff became muddled, its motivations became clearer.

In a June 27, 1994 letter to defense attorney Neuner, Longacre walked a fine line between pushing the case to settlement by making concessions and maintaining the image of a strong legal position. He wrote:

“I write somewhat reluctantly at this time because I fear that your clients may thus conclude that Dr. Pallin is close to throwing in the towel, and this letter may be viewed as a last ditch effort before that happens. In that regard I can only say that your clients should be able to see that Dr. Pallin feels just as strongly that he is in fact doing the

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<sup>25</sup> The pending motions were plaintiff’s Motion to Compel, defendants’ motion to compel Pallin’s deposition as an expert witness and to extend the discovery period, and the defendants’ motion to add the charge of inequitable conduct. Opinion and Order (rendered 5/12/94).

<sup>26</sup> Opinion and Order, p. 2.



right thing as do your clients and pioneering the way for others to follow. That being the case he just isn't about to give up."<sup>27</sup>

Longacre mentioned the "raging" public debate, especially among ophthalmologists, and acknowledged two central issues in the debate: whether a surgeon can sue another surgeon for patent infringement and whether medical patents should be abolished. However, Longacre set *Pallin v. Singer* apart from the public debate and raised a practical matter for the movement against patenting medical methods:

"These two issues don't seem to me to be ones which are going to be resolved in the context of this law suit where the issue is solely one of prior art and level of proof in the art. If Dr. Pallin does not prevail, and we certainly expect he will, some other surgeon will...be back in the future to have another go. Will Singer then ride out to the rescue again, and again, and again? As a practical matter can he achieve his objectives attacking these patents one at a time?"<sup>28</sup>

Longacre said the work of Gills did not constitute the clear and convincing evidence needed to invalidate a patent, and he recognized that Singer understood this. Longacre believed infringement was "unquestionable" and pointed to Singer's "promotion of this invention" and the acceptance of the invention among ophthalmologists as demonstrative of "unobviousness in spades."

Whether or not this was a bluff, it was clear that Longacre wanted to resolve this case. Thus, he appealed to Singer's ego, moral sensibilities, and aspirations, writing that Singer was free to speak his mind and to advance his objective of abolishing medical method patents. His appeal was offered in concessions on previous offers:

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<sup>27</sup> 6/27/94 Letter from Longacre to Neuner (Exhibit C) in Plaintiff Pallin's Opposition to Defendants' Motion for Leave to File Summary Judgment Motion Out of Time (filed 9/22/94), p. 1.

<sup>28</sup> 6/27/94 Letter from Longacre to Neuner, p. 1-2.



“With all of this in mind we are agreeable to a settlement which promotes your clients goals of embracing a political debate within the profession and without, and of ensuring that Dr. Singer’s goal that the Frown incision remain available to everyone is attained. Thus, we are prepared in addition to the settlement terms previously advanced to agree as follows:

1. Dr. Pallin will agree that he will not in the future seek any legal or administrative action which would stop anyone from using the technique. In short he will give up his right to pursue an injunction not only against Dr. Singer which he has already done, but against everyone. Further, he will agree that any royalty he might seek against others will be nominal in nature, along the lines he testified to in his deposition;
2. Dr. Pallin will further agree that he will take no action of any sort against those who merely teach or espouse using the technique or anything else, regardless of whether they are paid for their teaching or not.
3. We will agree to a full scale debate at the next meeting [unspecified professional society meeting] which I believe will be in the Fall in San Francisco. The debate could be between the principals, Dr. Pallin and Dr. Singer, between the lawyers, or both. I think that the society would agree to a prominent position on the program, perhaps on Sunday afternoon. Such a discussion, free





from the personal interests and constraints of this law suit, will likely be much more productive than otherwise.

4. Dr. Singer as we have said has played a prominent role in popularizing the incision. Presently, we estimate about half of the surgeons use the technique. Dr. Pallin would agree to work to make sure that Dr. Singer gets full credit for his contributions.
  
5. Dr. Singer remains free to speak his mind with regard to this subject totally free of any constraint or threat from the patent laws. As long as Dr. Singer doesn't slander Dr. Pallin he can say anything he wants without fear of suit, and this would then apply to everyone."<sup>29</sup>

Finally, Longacre expressed his belief that Pallin and Singer are both honest people who both believe they have the welfare of their patients and fellow ophthalmologists in mind, and he suggested that the two ophthalmologists might have a direct discussion to clear the air.<sup>30</sup> This direct discussion never took place, but the exchange of letters continued.

Longacre wrote to Neuner again on July 26 and conceded even more ground on settlement terms. The plaintiff unilaterally granted a license and assumed the defense would dismiss the lawsuit. Just like the attempt to limit the defense to one expert witness, it was another effort to entice the defense with a unilateral move, which the plaintiff hoped the defense would match. But the defense was not legally bound to do so, and it did not yield. Meanwhile, the plaintiff never wavered from its position of asserting the validity of the Pallin patent.

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<sup>29</sup> 6/27/94 Letter from Longacre to Neuner, p. 2-3.

<sup>30</sup> 6/27/94 Letter from Longacre to Neuner, p. 3.



In reply letters to Longacre, Neuner's partner, Peter Manus, wrote that Longacre's proposal might be an agenda item for a meeting of the Board of Directors of the Hitchcock Medical Center a month later.<sup>31</sup> Manus then offered the defendants' terms for ending the current litigation:

“At present I can only reiterate our previous position that the defendants will continue to pursue this case until they have a resolution that includes a dedication of the Pallin patent to the public, or some equivalent step.”<sup>32</sup>

Referring to the unilateral license grant, Manus added that the plaintiff cannot dismiss the jurisdiction of the court or the counterclaims of the defense against their will. With the plaintiff hoping to resolve the case quickly and the defendants wishing to defeat Pallin's patent, settlement proved impossible.

Meanwhile, the chronology of sutureless incision development was refined (See Timeline 1B).

The defense initiated the next phase of *Pallin v. Singer* by requesting time to file a summary judgment motion.<sup>33</sup> The plaintiff filed opposition. In the plaintiff's view, the only real issue before the court was inequitable conduct. In its view, the “grab bag of reasons” offered by the defense for why Pallin's patent was invalid had been disavowed by the defense's own expert witnesses.<sup>34</sup> If ruled upon favorably, a summary judgment motion would end the case without a trial. The plaintiff asserted that the defense would back its motion for summary judgment with a “grab bag of invalidity arguments” supported

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<sup>31</sup> 7/29/94 and 8/2/94 Letters from Manus to Longacre.

<sup>32</sup> 7/29/94 Letter from Manus to Longacre.

<sup>33</sup> The plaintiff objected on the grounds of improper judicial procedure and the absence of a judicial purpose. The plaintiff charged that the defense would suffer nothing by a denied motion while the court would experience delay and increased costs. The defense filed its motion after the deadline specified in the joint discovery schedule (after 8/1, the date Judge Billings had designated as the revised last day of the discovery period in his May ruling). In its opposition memorandum, the plaintiff remarked that the defense was aware of the deadline specified in the joint discovery schedule and was even reminded of it by plaintiff's counsel. Plaintiff's counsel had also planned their schedules in anticipation of a pre-trial conference. The final procedural objection was that local rules for judicial protocol should not have been disregarded. Defendants' Motion for Leave to File Summary Judgment Motion Out of Time was not available in archived court records.

<sup>34</sup> It stated that one of the defense witnesses, Dr. Fine, had disagreed with his own deposition statement that Pallin's invention was obvious. Plaintiff Pallin's Opposition to Defendants' Motion for Leave to File Summary Judgment Motion Out of Time, p. 3.



by “hotly disputed facts,” and because these arguments would constitute issues at trial, the plaintiff argued to go directly to trial. But trial would not be an option yet.



## IX. Second phase of judicial proceedings

This phase of the case assumed a technical tone as the real battle was fought in the trenches between ophthalmologic experts while the attorneys packaged arguments and engaged in legal maneuvering. No matter how many expert witnesses could have been summoned, no one was certain of how the self-sealing incision worked. Thus, the experts, while defending their technical statements with confidence and ferocity, were at times really engaged in speculation. There were some legal about-faces. As the chronology of who invented what became better established (See Timeline 2A), the central issue of infringement shifted to an issue of anticipation, intensifying the need for Pallin to defend his patent. The sutureless incisions of other ophthalmologists, including Singer's, had predated Pallin's chevron incision. And the issues of patent interpretation and nonobviousness loomed larger as the defense would dispute the originality of the incision. Finally, Pallin's credibility would be challenged.

### Bringing Other Incisions to Light

The defense had previously denied infringement, but it never offered a technical comparison of the chevron and frown incisions, or a technical comparison of other incisions with these. However, in its Motion for Summary Judgment, the defense employed technical analysis as it argued that Pallin's work was obvious and was anticipated by prior art. Much of the technical analysis was based on facts presented by Drs. Paul Ernest, James Gills, and Jack Singer. However, these witnesses also provided analysis that was weak or had no bearing on patentability. The primary thrust of the defense's strategy lay in showing that Pallin's incision technique was not novel. The defense did not pursue other venues of legal debate, such as whether the technique constituted patentable subject matter or possessed utility (See Framework for Core Arguments A).

The defense made three background points as it looked to the incisions of McFarland, Gills, and Singer. First, the first person to invent need not patent his work. Second, previous inventors did not suppress, abandon, or conceal their work. And third, what infringes a patent after the patent is granted invalidates the patent if it occurred before the development of the patented invention. The third point was the conceptual linchpin of the defense's prior art argument. The plaintiff could accuse Singer of infringing





his patent if Singer had performed his first frown incision after Pallin had performed his first chevron incision. But if Singer had in fact performed his first incision before Pallin performed his, then Singer's work would anticipate, and therefore invalidate, Pallin's patent.

The defense claimed that other ophthalmologists (McFarland, Gills, and Singer) had employed features of Pallin's incision, including incision shape and location, as well as his tunnel into the anterior chamber of the eye. The defense also claimed that the internal corneal lip, not the geometric shape or location of the incision as Pallin had claimed, provided sealing strength. Gills' inverted V incision arose as the strongest component of the defense's argument for patent invalidity. (See Chart -- Incision Construction Debate and Core Arguments B)

*Expert Opinion: Dr. Paul Ernest*

A board certified ophthalmologist, Assistant Professor of Ophthalmology at Wayne State University, and the Director of the Mid Michigan Eye Center, Ernest educated the Court with his technical knowledge. Ernest sketched a brief history of ophthalmologic surgery,<sup>1</sup> shed light on the incisions of other ophthalmologists, explained his rationale for utilizing a corneal lip, and commented on a number of legal issues before the Court.<sup>2</sup> On the whole, Ernest thwarted the plaintiff's efforts. Ernest appeared overly critical of the chevron incision and hinted that he is morally opposed to enforcing patents on surgical techniques.

According to Ernest, Dr. McFarland conceived of a sutureless procedure in January 1990 and was credited as the first person to perform modern sutureless cataract surgery. McFarland developed his technique after observing a patient whose suture had come untied with no accompanying wound leakage, which demonstrated self-sealing. He made his incision four millimeters posterior to the limbus and parallel

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<sup>1</sup> Among the historical developments recounted by Ernest is Dr. John Shepherd's use of a horizontal mattress suture in the late 1980s. This suture did not result in suture-induced scleral compression, allowing more physiologic healing. Furthermore, the technique only required a single stitch. Ernest also noted that Dr. Stephen Siepser presented his sutureless Radial Transverse Incision at a March 1990 meeting of the American Society for Cataract and Refractive Surgery.

<sup>2</sup> Declaration of Paul H. Ernest, M.D. In Support of Defendants' Motion for Summary Judgment of Invalidity; Appendix C in Memorandum in Support of Defendants' Motion for Summary Judgment of Invalidity (filed 10/3/94).



to a tangent to the limbus (i.e., a “straight line” incision). He also made vertical cuts in the scleral tunnel to allow insertion of larger implants.<sup>3</sup>

Ernest modified McFarland’s method by adding a corneal lip component in February 1990. In his opinion, a scleral incision without a corneal lip was unsafe. Ernest recounted his own empirical research on cadaver eyes which showed that eyes with corneal lips withstood up to ten times more pressure than eyes with conventional scleral tunnel incisions. Perhaps more relevant to the case, Ernest found that frown and chevron incisions with “the **same internal construction (i.e., the same tunnel incision components)** behaved substantially the same, regardless of the shape of the initial perpendicular incision into the sclera, although the frown incision appeared to exhibit slightly more resistance to external pressure.”<sup>4</sup> (Original emphasis) It should be noted that Ernest did not prove that incision shape did not contribute to self-sealing; his work suggests this as a possibility. Ernest believed that the incisions of Pallin, Siepser, McFarland, and Singer, all of which used the conventional scleral tunnel, were not safely self-sealing. However, Ernest does not define safety for the purposes of sutureless incisions. Safety ranges along a continuum defined by clinical judgment and is not a binary state as Ernest appeared to portray to the Court. Even if Ernest were correct that the incisions of others are unsafe, a dubious assertion in light of the fact that other surgeons have performed hundreds of sutureless cataract operations without a corneal lip, he failed to acknowledge that safety has nothing to do with patentability. Under the guise of an issue of legality, Ernest tried to divert the court into an ethical arena.

In commenting on the legal issues in the case, Ernest wrote that Pallin’s use of the phrase “substantially self-sealing” is indefinite and “has no specific meaning to one skilled in the art.”<sup>5</sup> Yet, Ernest used the phrase, which he claims has no definite meaning, when he attempted to build a case for anticipation of the chevron incision:

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<sup>3</sup> These cuts create an accordion-like section of scleral tissue that expands when stretched, thus allowing the insertion of larger implants. Vertical cuts are also called relaxing cuts. Ernest learned of McFarland’s incision in January 1990.

<sup>4</sup> Ernest Declaration, pp. 7, 14.

<sup>5</sup> He also asks if the phrase means “safe.” Ernest Declaration, p. 9.



“Certainly, in the very least, Dr. Gills and Dr. Singer each invented as much as Pallin discloses in his patent. They each made the same initial incisions described by the Pallin patent and set forth in the patent claims. That is all that the Pallin patent claims require. Pallin’s alleged invention makes no contribution to the state of the art over the techniques of Dr. McFarland, Dr. Siepser, Dr. Gills, and Dr. Singer, all of which techniques were performed prior to Dr. Pallin’s alleged invention, and were shared freely with the profession. . . . More specifically, each scleral incision and scleral tunnel used by Drs. McFarland, Siepser, Gills, and Singer is “substantially self-sealing” to the same extent as the incision described, illustrated and claimed by Dr. Pallin.”<sup>6</sup> [Original emphasis]

If a patent’s specifications are unclear to skilled practitioners in the art, then the patentholder has not achieved the disclosure and enablement aim of patent law, and the patent is rendered unenforceable.

Ernest also asserted that Pallin’s patent does not teach a skilled practitioner how to create a self-sealing wound because it does not describe the corneal lip. Ernest misses the legal issue of invention disclosure. A patent must disclose an invention, however the inventor or patentholder might conceive of it, to enable one skilled in the art to practice or use the invention. In Pallin’s view, the corneal lip is not necessary for self-sealing and is not a part of his invention. Thus, he should not be required to disclose something that is not part of his conception and reduction to practice of the invention, even if Ernest is correct about the corneal lip as the mechanism of incision self-sealing.

Ernest commits a major mistake of legal perspective. When it suits his needs, which appear to be defeating Pallin’s patent on the basis of moral opposition to the non-sharing of medical knowledge, he looks squarely at the claims in Pallin’s patent, such as when he supports a case of anticipation by saying that other incisions meet Pallin’s claims. However, when he raises the disadvantages of Pallin’s incision

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<sup>6</sup> Ernest Declaration, p. 11.



(e.g. lack of safety due to no corneal lip), he attempts to build a case that goes outside the bounds of the patent.

Ernest put forth his strongest argument for patent invalidity when he commented on the legal issue of obviousness:

“In my opinion, based on my knowledge and experience in the art, the scleral groove “V” or inverted “V” technique as first practiced by Dr. Gills on March 19, 1990 and the frown incision technique as first practiced by Dr. Singer on March 20, 1990 both would have been obvious to a person of ordinary skill in the art of scleral tunnel cataract surgery from the prior art cataract incision techniques of others, including the work of Dr. McFarland and Dr. Siepser.”<sup>7</sup>

Ernest’s contributions informed the legal debate and provided a context for thinking about patent validity and anticipation. The safety issue aside, Ernest laid the groundwork for patent invalidity due to non-novelty and obviousness.

*Testimony: Dr. James Gills*

A 1959 graduate of Duke Medical School and full clinical professor at the University of South Florida, Gills worked at St. Luke’s Laser and Cataract Institute in Tarpon Springs, Florida. A prolific author, Gills had focused only on cataract surgery with lens implants for twenty years.<sup>8</sup>

Gills performed his first inverted V incision on March 19, 1990.<sup>9</sup> His initial uses of the incision were inspired by theoretical arguments that such an incision would facilitate easy instrument manipulation and provide wound strength:

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<sup>7</sup> Ernest Declaration, p. 11.

<sup>8</sup> Gills had been experimenting with incisions as early as the mid-1980s, when he and others attempted to create scleral tunnel incisions. In Gills’ view, many patients experienced bleeding and iris prolapses because he and his colleagues did not believe it important to enter the anterior chamber.





“Being an engineer, I thought it would be very much like a strut that would hold the wound firm by having a deeper incision on the side than centrally and would allow the phacoemulsifier greater ease to pass into the eye. And so we considered doing an inverted V suture...for ease of manipulation of an instrument in the eye and also for possible strength we thought at that time. But we did other studies later that showed that that was more theoretical than real.”<sup>10</sup>

The inverted V consisted of a 50% scleral depth V-shaped incision approximately 3.2 to 3.5 millimeters wide with the tip of the V approximately 1.5 to 3.5-4 millimeters from the limbus. Gills varied the angle of the V from almost 180 degrees to less than 90 degrees (See Chart -- Incision Construction Debate).

In early 1990, Gills realized that the outer shape of the scleral incision contributed little to the level of astigmatism or to the seal of the wound.<sup>11</sup> As a result, in 1992, he used the inverted V less often. Gills believed the most important element for sealing was the internal corneal seal, which contributed to wound tightness, prevented astigmatism, and barred entry of bacteria into the eye.<sup>12</sup>

Gills published his incision in his books, as well as numerous “throwaway journals.” He first reported the inverted V in his book on small-incision cataract surgery which went to press in August 1990 and was distributed later that year.<sup>13</sup> Page 129 of Gills’ book has an April 9, 1990 photograph of a patient’s eye on which an inverted V was placed on March 19, 1990 (about a month before Pallin’s first chevron incision).

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<sup>9</sup> In testimony, Gills stated that he performed his first inverted V in February or March of 1990. He and his assistant later confirmed March 19, 1990 as the date of the first inverted V. An operative note from 3/22/90 states that a “scleral groove V incision was made using a Diamond knife and a Greishaber blade.” Operative note is Exhibit 4 of Gills deposition.

<sup>10</sup> Gills deposition transcript, p. 8.

<sup>11</sup> Gills deposition, p. 10.

<sup>12</sup> Gills deposition, p. 21.

<sup>13</sup> Author does not have citation for this book. However, both the plaintiff and defendant refer to this 1990 book throughout the case.



The work of Gills emerged as the leading piece of evidence for the defense's prior art argument. The defense remarked that whether or not Gills' incision was self-sealing was irrelevant for considering summary judgment.<sup>14</sup> What was important was that Gills had done what the patent teaches by making a scleral incision that diverged from the limbus. However, the defense overextended itself when it stated that Gills' work essentially met every claim that was at issue in the lawsuit. Gills' incision was chevron-shaped and had a central point which was within the 1.5 to 3 millimeters range specified in Claim 1 of Pallin's patent (See Table – Contentious Patent Text).<sup>15</sup> But it did not possess a curvilinear configuration. However, the defense believed Gills' work met claims 7 and 22, both of which refer to an incision with a curvilinear configuration. The defense acknowledged that Gills had not made a curvilinear incision, but it claimed that Pallin had said that a curvilinear incision is equivalent to a chevron. Thus, by Pallin's spoken words, Gills met claims 7 and 22. However, issues of anticipation and infringement must be resolved within the confines of the patent claims and cannot rely on public statements. Claim 28 was met by the use of a scleral tunnel.

The defense noted that Pallin equated curvilinear and chevron (i.e. frown and chevron) when he was interested in establishing infringement. However, because it was becoming clear that Pallin may not have been the first to invent, he was now beginning to pay the price for having overextended the breadth of his claims earlier.

*Expert Opinion: Dr. Jack Singer*

Singer's incision reinforced the defense's case. Singer stated that, prior to 1990, 99% of his cataract surgeries used small incisions, phacoemulsification, and sutures. This changed after he viewed Stephen Siepser's film<sup>16</sup> of the radial transverse incision. Singer says he conceived of an incision that would admit large lenses (6-7 mm), require a single horizontal suture at most, and reduce wound slide and

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<sup>14</sup> Memorandum in Support of Defendants' Motion for Summary Judgment of Invalidity (filed 10/3/94), p. 26.

<sup>15</sup> In Ernest's view, the McFarland incision also met the requirements of claim 1 of Pallin's patent. McFarland made an incision with a central point 2 to 3 millimeters posterior to the limbus.

<sup>16</sup> The film was shown at *The Symposium on Cataract, IOL and Refractive Surgery* on March 4-7, 1990.



surgically-induced astigmatism.<sup>17</sup> Singer performed his first frown-shaped incision on March 20<sup>18</sup> and his second on March 27.<sup>19</sup> Singer placed a 10-0 nylon suture in a single horizontal stitch in both operations.<sup>20</sup>

Singer reported that he omitted the single suture when he began using a corneal component around February 1991. He saw the corneal component as equivalent to the suture in effecting safe self-sealing. Notably, Singer only created a *bona fide* sutureless incision in 1991.

According to the defense, Singer's incision, as practiced on March 20, 1990, met every patent claim at issue (See Chart -- Incision Construction Debate, and Table – Contentious Patent Text).<sup>21</sup> However, as with its presentation of Gills' work, the defense was unable to build an airtight case. Regarding Claim 1, Singer's frown incision was also a self-sealing episcleral incision, which was "as self-sealing as the incision described in the Pallin patent." Singer provided a means for making the incision in the form of an Alcon crescent knife and a 15-degree blade. The central point of the frown incision was 2 millimeters posterior to the limbus. Like the chevron, the frown incision extended away from the central point and extended laterally away from the curvature of the limbus. The Singer frown fulfilled the curvilinear configuration criterion contained in claim 7. By the aforementioned, claim 22 (an amalgam of claims 1 and 7) was also fulfilled by the Singer incision. Claim 28 consists of claim 22 and the addition of a scleral tunnel from the incision to the anterior chamber of the eye. Singer's incision possessed a shelved incision (scleral tunnel) from the incision to the anterior chamber. Thus, it appeared that Pallin's patent

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<sup>17</sup> Declaration of Jack A. Singer, M.D. In Support of Motion for Summary Judgment of Invalidity, pp. 3-4.

<sup>18</sup> Using an Alcon crescent knife, Singer made a "6 mm grooved and shelved incision" positioned two millimeters posterior to the limbus. "Grooved" referred to curving away from the limbus, and "shelved" referred to the portion of the incision that is the tunnel into the anterior chamber. Singer subsequently entered the anterior chamber and created a linear opening in the anterior capsule. The nucleus was emulsified and aspirated, and an IOL was inserted. Singer Declaration, p. 4 and 3/20/90 Operative Report.

<sup>19</sup> Singer dubbed his incision the "frown" after his second operation. Singer explained what was denoted by "frown" in his operative report: "The term 'frown incision' is a term I use to refer to the entire wound architecture including the initial grooved incision into the sclera and the shelved incision into the anterior chamber. The incision architecture has continued to evolve, however, and the term 'frown incision' has continued to be used by me to refer to the incision over its entire evolution because the initial grooved incision in the procedure has always been a curved line that extends away from the limbus." Singer Declaration, p. 7.

<sup>20</sup> The higher the size number, the finer the suture (less cross-sectional area). Today, 10-0 sutures are routinely used in cataract surgery.



was doomed to be invalidated because Singer did what was specified in claims 1, 7, 22, and 28 of Pallin's patent. However, Singer had used a suture whereas Pallin had not.

The defense took issue with the plaintiff's argument that using a suture is not using the chevron incision technique. The defense referred to col. 4, lines 41-45 of the patent which allow for the use of a single suture when large lens implants up to 6mm are used (See Table – Contentious Patent Text). For his first incision, Singer used a 6mm non-foldable lens with one suture.<sup>22</sup> But, as the plaintiff would raise later, anticipating an invention requires anticipating every feature of that invention, specifically every claim of the patent.

### *Arguing obviousness by establishing equivalence*

Turning to the issue of obviousness, the defense argued that primary considerations in deciding nonobviousness<sup>23</sup> (i.e., is the invention obvious to an ordinary ophthalmologist?) overwhelmed secondary considerations<sup>24</sup> (i.e., does the invention deserve a patent due to marketplace circumstances, even if it is obvious to an ordinary ophthalmologist?). Therefore all claims are obvious to an ophthalmologist of ordinary skill. The practitioner of ordinary skill was defined as an ocular surgeon performing scleral tunnel cataract surgery in 1990. The defense wrote that Pallin's chevron, "Gills' chevron," the frown, and the straight line incision all diverge from the limbus, as defined by the Pallin invention, and because Pallin had testified to the equivalence of the chevron, frown, and straight line incisions, these incisions also "must provide the stated advantages of the alleged invention, whether defined generally as in claim 1 or more specifically, as a "curvilinear" episcleral incision, in claims 7, 22, and 28."<sup>25</sup> The defense asserted that the work of McFarland, Gills, and Singer was "corroborated and uncontroverted." It also noted that these physicians contributed their work to the medical community and made no efforts to suppress, abandon, or

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<sup>21</sup> It cites a set of exhibits composed by Paul Ernest which compare features of the individual incisions of McFarland, Gills, and Singer to the patent claims at issue. Exhibit 2 in Memorandum in Support of Defendants' Motion for Summary Judgment of Invalidity.

<sup>22</sup> Exhibit 2 in Memorandum in Support of Defendants' Motion for Summary Judgment of Invalidity, Footnote 12, p. 28.

<sup>23</sup> Determining scope and content of prior art, differences between prior art and claims at issue, and level of ordinary skill in the pertinent art.

<sup>24</sup> Commercial success, long-felt but unsolved needs, and failures of others to invent.

<sup>25</sup> Memorandum in Support of Defendants' Motion for Summary Judgment of Invalidity, p. 31.





conceal their work prior to the alleged date of Pallin's first chevron incision.<sup>26</sup> Seeing no genuine issue of material fact as to the invalidity of the patent claims at issue, the defense requested summary judgment.<sup>27</sup>

### Rejecting a Cornucopia of Features

On December 5, 1994, the plaintiff filed opposition to the defense's motion for summary judgment.<sup>28</sup> The plaintiff reminded the court and the defendants that a U.S. patent is presumed valid, and a challenger must overcome this presumption with clear and convincing evidence, which the plaintiff believed was lacking. The plaintiff picked apart the defense's overall argument by attacking the defense's non-patent-related assertions<sup>29</sup> and focusing on issues of patent interpretation, prior art, and nonobviousness (See Core Arguments B).

### *Discrediting and defining*

Most troublesome for the defense was very poor witness credibility and the possibility of foul play with respect to Dr. Gills. The plaintiff noted that Gills' 1994 testimony contradicted statements he made in his 1990 book. In his book, Gills states that incision dimensions are critical, yet the plaintiff noted that Gills' operation notes from 1990 do not mention incision dimensions.<sup>30</sup> However, what the plaintiff failed to note is that four years had passed between the publication of Gills' book and his deposition. It appears that Gills had since realized, correctly or incorrectly, that a mechanism, other than incision dimensions, is responsible for self-sealing. The plaintiff also noted that Gills' incision was not measured by either himself

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<sup>26</sup> Memorandum in Support of Defendants' Motion for Summary Judgment of Invalidity, p. 32.

<sup>27</sup> On 10/12/94, Judge Billings issued an order which noted that defendants were tardy in filing their motion requesting leave to file their summary judgment motion after the deadline specified in local rules. However, because the plaintiff would suffer no prejudice due to the defendants' delay, the Court granted the defense's request. On 10/18/94, the plaintiff filed a motion to extend time for responding to the "formidable nature of the present Summary Judgment filing, i.e. its sheer bulk comprising over 400 hundred pages, several expert declarations, associated exhibits, and deposition excerpts." Billings grants this motion and later grants a motion for the defense to extend time to respond to the plaintiff's response. Motion for Extension of Time for Plaintiff to Respond to Defendant's Motion for Summary Judgment (filed 10/18/94), p. 2.

<sup>28</sup> Plaintiff's Memorandum in Opposition to Defendant's Motion for Summary Judgment of Invalidity (filed 12/5/94).

<sup>29</sup> Among the non-patent-related points was Pallin's belief that the mechanism for incision self-sealing lies in the length to width ratio of the scleral tunnel and not the internal corneal lip as Ernest asserted.



or his assistant at the time of surgery but rather measured in a post-operative photograph. To make matters worse for the defense, Gills revealed in deposition that he “estimated and guesstimated” distances and that actual ruler measurements were rarely done, thus weakening the credence of his claims that his incisions were placed within the range specified in Pallin’s patent.<sup>31</sup> But he did introduce the potentially relevant issue of measurement reference when he stated that any “reference to a distance from the limbus is necessarily imprecise, because the limbus itself is an area having a width of about 0.5 to 1 mm, depending on the patient.”<sup>32</sup> (See Figure 1) Worst of all, the photo provided by Gills to show the position of his incision did not match that on page 129 of his book as he had claimed. Gills was easily portrayed as inconsistent, imprecise, and perhaps deceptive. The plaintiff concluded that the story of Gills’ incision did not constitute clear and convincing evidence to justify summary judgment. It called for a jury to assess Gills’ credibility and to determine if he actually anticipated Pallin’s invention.<sup>33</sup>

Turning to patent interpretation, the plaintiff disputed the defense’s assertion that “substantially self-sealing” was poorly defined by stating that Pallin’s patent claims, specifically lines 9-16 of column 4,<sup>34</sup> clearly covered a sutureless and water-tight incision. And the plaintiff cited cases in which “substantially” was taken to mean as close as humanly possible.<sup>35</sup>

The defense appeared to be classifying the Pallin incision as one that requires sutures because the Pallin patent clearly specifies that it is permissible to use a suture when implanting large lenses, 6mm or above. The plaintiff argued that the Pallin incision is a sutureless one for classification purposes, even if a

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<sup>30</sup> Plaintiff’s Memorandum in Opposition to Defendant’s Motion for Summary Judgment of Invalidity, p. 14.

<sup>31</sup> From Gills’ deposition: “Q [Counsel for defense]: Is the distance from the limbus measured exactly during operations? // A. Sometimes we do when were doing studies, otherwise we did it kind of free, you know, kind of estimated and guesstimated it, that it may vary from, you know, half a millimeter one way or the other.” Gills deposition, p. 18; Gills’ assistant, Sherry Gillis, only exacerbated the problem. When asked how far from the limbus the inverted V incision is made, she replied, “Just by looking at the eye and judging from past experience.” Gillis deposition, p. 11.

<sup>32</sup> Gills deposition, p. 9, Footnote 6.

<sup>33</sup> Plaintiff’s Memorandum in Opposition to Defendant’s Motion for Summary Judgment of Invalidity, pp. 30-31.

<sup>34</sup> Lines 9-16 of column 4 read: “The configuration wherein linear portions...of incision 22a [chevron incision] and lateral portions...of incision 22b [curvilinear incision] extend laterally away from the curvature of limbus...enable incisions 22a and 22b to be substantially self-sealing. When eye...is inflated following surgery, the force vectors acting on incisions 22a and 22b induce closure of scleral tunnel...so that incisions 22a and 22b become water-tight and require no sutures for sealing.”



suture may be used for large implants. The question becomes: is the Pallin invention a suture-using incision or a sutureless incision for which a suture can be used under special circumstances? The issue of definition is important for the enablement requirement of patent law. If it could be shown that Pallin did not disclose, or did not define in this case, sufficiently to enable a skilled practitioner to practice the chevron incision method, his patent could be invalidated. The defense did appear to be broadening the scope of Pallin's patent but it raised a critical issue which softened Pallin's claims as to the nature of his invention.

### *Debunking prior art*

The plaintiff mounted a vigorous attack on the defense's prior art argument and concluded that the incisions of others, taken individually, did not anticipate Pallin's invention. Therefore, Pallin's patent was valid. The thematic spearhead of the plaintiff's attack lie in the following: "It is axiomatic that for prior art to anticipate..., it has to meet every element of the claimed invention within its four corners, and that such determination is one of fact."<sup>36</sup> Thus, in order to anticipate the chevron, an incision must meet every feature of the chevron (See Chart -- Incision Construction Debate). Even if the plaintiff could not prove its assertions, if it could persuade the Court that there were genuine issues of fact to be resolved, then it would be granted a jury trial. The plaintiff tacitly acknowledged that the incisions of others predated Pallin's incision and therefore aimed to show that these ophthalmologists did not conceive of and disclose Pallin's invention; that their incisions were not reduced to practice before Pallin's invention; and that their incisions were abandoned, suppressed, or concealed. A successful case would effectively nullify the existence of the other incisions as far as the patent statutes were concerned.<sup>37</sup>

The plaintiff's conception argument hinged on showing that the incisions of others were not the same as Pallin's incision. In its view, McFarland's incision did not teach the Pallin technique because it used relaxing cuts and a straight-line incision located 3-4 millimeters from the limbus. Ernest had added a

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<sup>35</sup> Plaintiff's Memorandum in Opposition to Defendant's Motion for Summary Judgment of Invalidity, p. 17. Defense cites *Ex parte Wheller*, 163 USPQ 569 (Patent Office Board of Appeals 1968).

<sup>36</sup> The defense cites numerous cases to support its statement. Plaintiff's Memorandum in Opposition to Defendant's Motion for Summary Judgment of Invalidity, p. 22.

<sup>37</sup> Section 102 (g) specifies enablement.



corneal tissue component to McFarland's incision and later moved the incision to two millimeters posterior to the limbus, which was within Pallin's specified range of 1.5 to 3.0 millimeters. However, in the plaintiff's view, neither McFarland nor Ernest taught the Pallin invention because they did not conceive of (or reduce to practice) the "limbal diverging incision" and its location at the apex as described in Pallin's patent. (Original emphasis)<sup>38</sup>

The plaintiff asserted that Singer's incision also did not constitute a conception of Pallin's "water-tight sutureless incision invention" because it required a stitch for wound sealing. The plaintiff also asserted that Singer did not reduce the idea of a self-sealing incision to practice because his "single-stitch work [was] defective on its face as a reduction to practice of a sutureless water-tight incision. It did not work, he knew it at the time, and he put in a stitch to close."<sup>39</sup>

The plaintiff argued that McFarland and Ernest did not disclose sufficiently to invalidate Pallin's patent. Particularly damaging for McFarland was the statement of one of the defense's expert witnesses. Howard Fine stated in deposition that he felt McFarland's description was not adequately detailed.<sup>40</sup> This implies that because McFarland did not disclose sufficiently to enable a skilled practitioner in the field to practice the invention, his disclosure did not constitute a showing of prior art under the patent statutes. The plaintiff said Ernest failed to disclose because the defense did not provide evidence of Ernest's grand rounds presentation at Wayne State University in February 1990. This supposed weakness in the defense's argument could have been addressed quickly with records of grand rounds and witnesses who attended grand rounds.

The plaintiff then attacked the strongest component of the defense's prior art case – Gills' inverted V incision. Citing recent infringement cases and a popular patents textbook, the plaintiff wrote that

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<sup>38</sup> The plaintiff explicitly noted that although Ernest moved his incision to within the range specified by the Pallin patent, Ernest did not use a diverging incision and therefore did not anticipate Pallin's invention because it did not meet "every element of the claimed invention within its four corners." Plaintiff's Memorandum in Opposition to Defendant's Motion for Summary Judgment of Invalidity, p. 27.

<sup>39</sup> Plaintiff's Memorandum in Opposition to Defendant's Motion for Summary Judgment of Invalidity, p. 36.

<sup>40</sup> Plaintiff's Memorandum in Opposition to Defendant's Motion for Summary Judgment of Invalidity, pp. 13-14. The plaintiff excerpted the following from p. 40 of Fine's 9/1/94 deposition in Eugene, Oregon: p. 40: "Q (White): In reviewing this article in your judgment is there sufficient information here for someone to do what is described here? // A. Well, I think that I didn't think it was – it was adequately detailed, that I wanted to do it, that I wanted to try it."





“conception requires ‘a definite and permanent idea of a complete and operative invention, as it is hereafter to be applied in practice.’” It proceeded to build a case that Gills had not fulfilled this standard because he did not conceive of the necessary elements of the Pallin incision before Pallin did.<sup>41</sup> Gills had allegedly placed his inverted V incision within the range specified in the Pallin patent, but in his 1990 book, Gills states that an incision position of 3-4 millimeters posterior to the limbus is critical. The plaintiff noted that if Gills had conceived of the Pallin invention, then he was teaching away from it. Gills eventually reduced use of the inverted V because he concluded that the shape and location of the incision had little effect on astigmatism and self-sealing.<sup>42</sup> The plaintiff concluded that Gills had abandoned his work and even tried to suppress or conceal details of the inverted V. The plaintiff exaggerates. Gills did not give up on the inverted V entirely. He merely used it less often. Nevertheless, over time he also placed importance on features such as tunnel length, corneal valve, and perfect scleral flaps in self-sealing. Given Gills’ unclear or changing conception of his incision and his assertion that incision shape and position were not critical to self-sealing, the plaintiff concluded that Gills had not conceived of the necessary elements of Pallin’s invention before Pallin had.

The plaintiff explicitly noted that conceiving the idea of an invention is insufficient for the invention to exist as prior art under the patent statutes. The idea must be reduced to practice by either a process of actual reduction, in which the idea is embodied in a developed product or process, or by constructive reduction, in which the inventor filed for a patent. Noting that none of the alleged prior inventors of a sutureless incision had filed for a patent, the plaintiff stated that Gills relied on features other than those Pallin relied on in creating a self-sealing incision, and therefore Gills had not reduced the Pallin invention to practice.

Arguments about lack of reduction to practice and about abandonment, concealment, and suppression merely supplemented the central arguments about conception. The plaintiff wrote:

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<sup>41</sup> Plaintiff’s Memorandum in Opposition to Defendant’s Motion for Summary Judgment of Invalidity, p. 28.



“It is clear on the foregoing record that while each of Drs. McFarland, Ernest, Gills and Singer conceived of an incision, to varying degrees of completeness, none conceived of the Pallin invention. The record shows that the prior art offered by defendants either left out features, relied on other features, didn’t record what was actually done and/or simply retraced single stitch work....Instead, the art presented is a cornucopia of features which each user relies on in some respect for a given effect, i.e., reduced astigmatism, sealing quality, corneal valve, long narrow tunnel, relaxing cuts, perfect scleral flaps, etc.”<sup>43</sup>

In the plaintiff’s view, the prior art offered by the defense could not invalidate a U.S. patent under the conception standard.

*Casting the chevron as nonobvious*

The plaintiff then sought to bolster its case for the nonobviousness of the Pallin invention by commenting on the pioneering status of the chevron incision in 1990, showing how the Pallin incision overcame the limitations of the Gills incision, and noting that Singer’s original incision did not self-seal. The plaintiff also stated that the defense did not develop and present its arguments for secondary considerations of obviousness as dictated by legal precedent (the “*John Deere* case”).<sup>44</sup> This shortcoming would be an Achilles heel for the defense.

In the plaintiff’s view, sutureless incisions, as a whole, were nonobvious. Sutureless wounds were “far removed” from the state-of-the-art in cataract surgery in 1990, and one of the first surgeons to use a

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<sup>42</sup> Plaintiff’s Memorandum in Opposition to Defendant’s Motion for Summary Judgment of Invalidity, p. 29.

<sup>43</sup> Plaintiff’s Memorandum in Opposition to Defendant’s Motion for Summary Judgment of Invalidity, pp. 33-4.

<sup>44</sup> *Graham v. Deere, Co.* 383 U.S. (1966) sets forth a framework for secondary considerations of nonobviousness.



sutureless incision method was branded a quack.<sup>45</sup> The plaintiff also noted that some of the defense's expert witnesses had expressed disbelief and awe that a sutureless incision was possible. The plaintiff cited the preface of Gills' 1990 book in which Gills writes that sutureless surgery is "revolutionary." Gills had also testified to the effect that those who engaged in sutureless surgery at that time were ahead of the pack.<sup>46</sup>

But the plaintiff went beyond simply asserting the nonobviousness of sutureless incisions. It highlighted the advantages of the Pallin technique over other incisions, particularly Gills' incision. The plaintiff pointed out that Gills had to use straight 6-6.5 millimeter incisions for hard lenses, rely on "perfect scleral flaps,"<sup>47</sup> and employ an internal corneal valve to achieve self-sealing, whereas the Pallin invention could admit hard lenses and did not employ an internal corneal valve. Curiously, even though the plaintiff had previously stated that the internal corneal valve is not responsible for self-sealing, it used this cause-and-effect relationship in order to set the Gills self-sealing incision apart from the Pallin self-sealing incision. Once again, technical opinion was unclear on the mechanism responsible for self-sealing.

Having addressed the Gills incision, the plaintiff then constructed a more damaging scenario of the development of Singer's incision. Beginning with the plaintiff's claimed premise<sup>48</sup> that Singer admitted that his first incision did not self-seal, the plaintiff logically constructed a scenario in which Singer unsuccessfully attempted to create a sutureless incision, and then failing in this effort, modified his incision slowly over time until he achieved suturelessness, but after Pallin had already demonstrated the self-sealing features of the chevron incision. Pallin's attorneys stated, "It was not until he [Singer] changed his technique, to fall within the Pallin patent claims and specification teachings, that his incision method

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<sup>45</sup> Referring to Dr. Michael McFarland. Plaintiff's Memorandum in Opposition to Defendant's Motion for Summary Judgment of Invalidity, p. 43, 48.

<sup>46</sup> Plaintiff's Memorandum in Opposition to Defendant's Motion for Summary Judgment of Invalidity, p. 50.

<sup>47</sup> As the defense later pointed out in its response to the plaintiff's opposition memo, "perfect scleral flaps" is merely one name for the flap of scleral tissue that is created when one excises surface scleral tissue in order to make an incision in the scleral tissue underneath. Even Pallin creates such "flaps."

<sup>48</sup> The plaintiff cites Defendant appendix D, Section 5 which are Singer's clinic notes. This author found Singer's handwriting to be illegible; thus, the plaintiff's claimed premise is neither confirmed nor rejected.



resulted in a self-sealing incision.”<sup>49</sup> If the plaintiff’s assertion were proven true, then Singer’s invention would be cast from the realm of prior art back to the realm of infringing activity, and Pallin would thus have to fight the prior art of McFarland, Ernest, and Gills on one side of the invention timeline and Singer’s frown incision on the other side (See Timeline 2B). If Singer’s invention could be cast as an infringing activity, then the defense’s arguments to the effect that the chevron incision mimics the frown incision could be used against the defense.

The plaintiff reinforced its nonobviousness argument by assessing secondary considerations of nonobviousness. Pallin’s attorneys wrote:

“The facts of this case clearly establish that prior to the Pallin invention there existed a long felt, but unsolved need, to provide a sutureless cataract surgical procedure which did not hinder tool manipulation (i.e. eliminate “oarlock” effect) or detrimentally affect the eye’s vision after surgery owing to induced astigmatism. Few others in the field even attempted to solve this need by April 1990, and efforts of those few who did attempt it and tried to find any lasting method (McFarland, no more relaxing cuts or long length, and Gills, abandoned inverted “v”) failed.”<sup>50</sup>

They further argued that because 1/3 of ophthalmologic surgeons had adopted the sutureless incision method and because Singer was making “strenuous efforts” to invalidate Pallin’s patent, the concept of the diverging incision must be nonobvious.<sup>51</sup> However, what the plaintiff failed to realize, or to acknowledge, is that the annual Leaming survey, which details ophthalmology practice patterns, reports the adoption of a

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<sup>49</sup> The plaintiff stated that the technique presently used by Singer was modified substantially from his work in March 1990 and now fell within the scope of the Pallin patent. Plaintiff’s Memorandum in Opposition to Defendant’s Motion for Summary Judgment of Invalidity, p. 48.

<sup>50</sup> Plaintiff’s Memorandum in Opposition to Defendant’s Motion for Summary Judgment of Invalidity, p. 51.

<sup>51</sup> Citing Leaming survey which says 1/3 of surgeons have adopted a sutureless method. Plaintiff’s Memorandum in Opposition to Defendant’s Motion for Summary Judgment of Invalidity, pp. 51-2.





*sutureless method*, not necessarily *Pallin's* sutureless method, or any one surgeon's method. Furthermore, Singer's efforts to invalidate the patent, which would appear to be motivated by his ethics, do not confer nonobviousness on Pallin's invention as the plaintiff asserts. Singer may have made "strenuous efforts" to invalidate the patent because he believes that Pallin's invention *is* obvious and therefore does not deserve a patent.

Nevertheless, in spite of previous surgeons who had taught some features of Pallin's invention, it was not apparent that any one surgeon had taught all features of Pallin's invention. In conclusion, the plaintiff wrote that Pallin's "patented invention is not obvious since the work of others cannot be combined to create the invention, even in selective hindsight."<sup>52</sup> The plaintiff had weakened the defense's prior art argument by distinguishing Pallin's chevron incision from the incisions of others, questioning the credibility of Gills, who was the defense's "smoking gun," and casting Singer's frown incision as an after-the-fact imitation.

### Casting the Last Stone

The defense cast the last stone in the second phase of the court case by rebutting the plaintiff's opposition to its motion for summary judgment (See Core Arguments B).<sup>53</sup> In piecemeal fashion, the defense responded to the plaintiff's charges and assertions regarding procedural matters,<sup>54</sup> the definition of "substantially self-sealing,"<sup>55</sup> McFarland's incision, Gills' incision, and Singer's incision. It also alleged that Pallin held inconsistent interpretations and offered unsupported arguments. Pallin was slowly being

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<sup>52</sup> Plaintiff's Memorandum in Opposition to Defendant's Motion for Summary Judgment of Invalidity, pp. 52.

<sup>53</sup> Defendants' Reply Memorandum in Support of Their Motion for Summary Judgment (filed 1/4/95).

<sup>54</sup> Responding to the plaintiff's charge that the defense did not offer arguments for obviousness in the format provided by *Graham v. Deere*, the defense noted that alternative formats for presenting obviousness arguments exist, as dictated by alternative case precedents. Defendants' Reply Memorandum in Support of Their Motion for Summary Judgment (filed 1/4/95), p. 14.

<sup>55</sup> Regarding the seemingly unresolvable issue of the definition of "substantially self-sealing," the defense noted that Pallin defined the phrase as "watertight and sutureless" and yet pointed out that his patent teaches the practitioner to use a suture in large lens placement. Defendants' Reply Memorandum in Support of Their Motion for Summary Judgment (filed 1/4/95), p. 20.



confined by his own statements as the defense's rebuttal put forth poignant arguments supported by detailed patent analysis.

### *Supporting Gills*

Perhaps because it sensed its own vulnerability with respect to the centerpiece of its prior art argument, the defense aggressively affirmed the validity of Gills' testimonial and photographic evidence and added that Pallin's testimony regarding the photograph established Gills' incision as prior art. On the suspicious circumstances surrounding Gills' photograph, the defense wrote:

“As to the possible discrepancy between Exh. 5 photograph as to which Dr. Gills testified, and the photograph on page 129 of Gills' Chapter 8, this may reflect a misunderstanding of counsel. Dr. Gills is investigating, but in any event Dr. Gills remains consistent and accurate.”<sup>56</sup>

Perhaps knowing that it could not disprove any wrongdoing at the time of writing its court memorandum, the defense attempted to use Pallin's testimony against him in an effort to salvage some evidentiary validity in Gills' photograph.<sup>57</sup> When shown Gills' photograph during deposition, Pallin had apparently said the distance of the incision from the limbus was “at least 3.0 mm.” The defense maintained that this value fell within the range specified in the Pallin patent claims. In the defense's view, “Pallin's “measurement” proved nothing about the exact position of Dr. Gills' incision, **except that it is in the claimed range.**” (Original emphasis) The defense was technically correct. The *low value* of Pallin's estimate lay within the range specified by his patent. But Pallin stated a range of measurement, which was a visual estimate of a photograph he did not take. On a second look, Pallin might have changed his estimated range to contain a low value greater than 3.0 mm. Therefore, the defense appeared to be overextending itself by saying that

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<sup>56</sup> Defendants' Reply Memorandum in Support of Their Motion for Summary Judgment (filed 1/4/95), p. 7, Footnote 5.

<sup>57</sup> Defendants' Reply Memorandum in Support of Their Motion for Summary Judgment (filed 1/4/95), p. 7.



Pallin's deposition statement established anticipation by Gills' incision. The photographic centerpiece of the defense's prior arguments lay in question.

*Reasserting prior art and obviousness*

Pallin had asserted that McFarland's incision did not constitute prior art because McFarland had made relaxing cuts in the floor of the scleral tunnel. However the defense correctly stated that Pallin's patent did not restrict the dimensions or construction of the scleral tunnel, or prohibit the use of relaxing cuts.

The defense then delivered perhaps the strongest version of its argument that Singer's use of a suture fell within the claims of Pallin's patent. It stated that Singer had used 6.0 millimeter and 7.0 millimeter lenses in his March 1990 surgeries. Because both lenses were large lenses, greater than 6.0 millimeters in diameter, the incisions through which they were placed could be sealed with a suture according to Pallin's patent.<sup>58</sup>

Regarding the plaintiff's view that Singer had changed his incision over time to acquire the self-sealing properties of the chevron incision by doing what is taught in the Pallin patent claims, the defense begged to differ:

"Moreover, with respect to Dr. Singer's frown incision, Pallin is flat wrong on the facts. Pallin alleges that Dr. Singer changed his frown incision in 1991 to include a widening tunnel (non-parallel sides) and a "stretch" frown, where the width (chord length) of the frown incision is less than the diameter of the lens being inserted. The fact is that Dr. Singer always used a widening tunnel from March 1990 onward."<sup>59</sup>

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<sup>58</sup> Defendants' Reply Memorandum in Support of Their Motion for Summary Judgment (filed 1/4/95), p. 21, Footnote 21.

<sup>59</sup> The defense also wrote: "Accordingly, the Pallin drawing of the Singer Frown incision at Opposition, page 31 is factually incorrect. Moreover, even as drawn by Pallin, the Singer incision anticipates the



Responding to the assertion that Gills had abandoned his incision, the defense wrote that neither Gills nor McFarland and Singer abandoned their work but merely changed their technique.<sup>60</sup> The defense commented that McFarland had moved his incision into the range specified in the Pallin patent even before Pallin created his first chevron incision.<sup>61</sup>

In an attempt to invalidate Gills' work as prior art, Pallin had distinguished his incision by saying that it could admit non-foldable lenses whereas the Gills incision could not. But this was irrelevant to patentability. The defense observed that "the patent claims are silent as to lens type. Pallin did not limit his claims to a non-foldable lens."<sup>62</sup> To place non-foldable lenses, Gills used a straight-line incision (6-6.5 millimeters in length) and not the inverted V. But, the defense noted that Gills' inverted V incision was 3.5 millimeters in width which is the same incision width taught by the Pallin patent for inserting a 5.0 x 6.0 millimeter non-foldable ovoid lens.<sup>63</sup> It wrote, "There was nothing about the admitted Gills incision which would have prevented the insertion of a non-foldable lens."<sup>64</sup> Although the defense did not make this point, it is worth noting that this counterargument suggests that Gills did not find it easy or safe to insert a non-foldable through a 3.5 millimeter incision and therefore used a 6-6.5 millimeter straight-line incision for these. Thus, two ophthalmologists diverged in clinical practice given the same clinical situation.<sup>65</sup>

### *Challenging the credibility of Pallin and his patent*

Having addressed the major arguments put forth by the plaintiff, the defense introduced a new twist to the case by showcasing a synthesis of Pallin's testimony, his patent claims, and plaintiff's legal

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asserted claims Defendants' Reply Memorandum in Support of Their Motion for Summary Judgment (filed 1/4/95), p. 13, Footnote 10.

<sup>60</sup> Defendants' Reply Memorandum in Support of Their Motion for Summary Judgment (filed 1/4/95), pp. 11-12.

<sup>61</sup> Defendants' Reply Memorandum in Support of Their Motion for Summary Judgment (filed 1/4/95), pp. 9-10.

<sup>62</sup> Defendants' Reply Memorandum in Support of Their Motion for Summary Judgment (filed 1/4/95), p. 8.

<sup>63</sup> Defendants' Reply Memorandum in Support of Their Motion for Summary Judgment (filed 1/4/95), p. 8. The defense cites column 4, lines 37-41 of the Pallin patent which reads: "For example, a solid ovoid biconvex lens implant having dimensions of 5 millimeters by 6 millimeters may be successfully inserted into an incision 22 ["22" refers to the chevron incision in the patent drawings] having a cord length of 3.5 millimeters without tearing incision 22." [Note: cord length is effectively the width of the incision.]

<sup>64</sup> Defendants' Reply Memorandum in Support of Their Motion for Summary Judgment (filed 1/4/95), p. 8, Footnote 6.





documents, which appeared to demonstrate confusion and inconsistency. The defense juxtaposed Pallin's contradictory statements about what practices his patent covered. Pallin was getting into trouble for expanding the breadth of his claims when he thought infringement was the central issue. However, the case was now mainly one of anticipation. Pallin was distinguishing his incision by identifying its supposedly unique components and supposed advantages over other incisions. However, these components and advantages were not described in his patent claims and thus, legally they could not be convincingly considered part of his invention. As both sides carefully scrutinized Pallin's patent, Pallin was being confined by his statements, and he had to struggle to extricate himself from a web of inconsistencies and contradictions.

The first problem for Pallin lie in his contradictory statements regarding what shapes of incisions his patent covered. In his deposition as a fact witness, he stated that his patent covered all scleral incisions except the smile.<sup>66</sup> (See Chart – Incision Shapes) In his deposition as an expert witness, when asked if a straight line would constitute an infringement under claim 1, he replied, “anywhere we speak about diverging from the limbus, a straight line would qualify.”<sup>67</sup> However, in the second phase of the case, Pallin claimed that his patent did not cover the straight line incision of McFarland (and Ernest). Pallin's deposition testimony is consistent with a view that the straight line incision of McFarland diverges because the limbus is curved and therefore as one moves laterally from the incision's midpoint, the points of the incision necessarily move farther away from the limbus. Thus, Pallin appears to be trying to have his cake and eat it too. The defense distills its argument in the following passage:

“Pallin makes various contradictory statements regarding “straight” or “linear” incisions. When it suits Pallin's interests, he uses the clear and natural meaning for the term “straight” or “linear”. He used “linear” in

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<sup>65</sup> Or less likely, Gills used an incision with a width that was actually less than 3.5 millimeters which made it difficult or unsafe to insert a non-foldable lens.

<sup>66</sup> “Smile” refers to the traditional curvilinear incision which is parallel to the curvature of the limbus. Pallin I deposition, pp. 194-95. Excerpt appended to Defendants' Reply Memorandum in Support of Their Motion for Summary Judgment (filed 1/4/95).

<sup>67</sup> Excerpt appended to Defendants' Reply Memorandum in Support of Their Motion for Summary Judgment (filed 1/4/95).



the patent at Col. 1, lines 18 and 56, and Col. 3, lines 49 and 50, without explanation. Pallin admits that Dr. McFarland made a “straight line” incision, i.e., “parallel to a line tangent to the limbus,”...and is certain that this “straight line” is the same “linear” shaped incision which he characterized in his patent as being part of the prior art. But when asked about infringement by other surgeons who presently use a linear or straight incision and, therefore, are potential infringers, he has no problem saying that because a limbus is curved, a straight incision “diverges” from the curved limbus.”<sup>68</sup>

But Pallin’s statements regarding the frown incision in particular weakened his position insofar as his testimony, and not the patent claims themselves, was concerned. He said that the reduction to practice of his inventive idea includes the chevron and frown incisions:

“Q. Do you believe that the chevron incision includes the frown incision? // A. Most definitely. // Q....[regarding the chevron incision,] you have always used it to connote an inverted V as the chevron incision, is that correct? // A. No, that is not correct. Let me refer you back to my testimony at the last meeting that we had in which I said that many of my incisions look more like a frown than a chevron. And that is part of what I described, that virtually every incision, at some point in the incision, will look like a frown because of the stretching

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<sup>68</sup> Defendants’ Reply Memorandum in Support of Their Motion for Summary Judgment (filed 1/4/95), p. 10. Note: “Fact 21” in the above passage refers to a summary document of the defense’s major premises and arguments.



and manipulating. // Q. Even a straight line will look like a frown, right? // A. Or a frown like a straight line, yes.”<sup>69</sup>

Thus, in Pallin’s view, the chevron subsumed the frown. However, if the chevron becomes a frown during and after surgical manipulation, the chevron is effectively equated with the frown incision. And Pallin equated the frown and straight line. The defense stated the implications of this line of thinking:

“Since Pallin himself relies on his first use of the “chevron” incision as a reduction to practice of the “frown” incision, he cannot argue **genuinely** that the “chevron” incision of Dr. Gills does not render obvious the claimed curvilinear incision, or that the frown incision of Dr. Singer does not render obvious the chevron incision.”<sup>70</sup>

Before it was known that Gills and Singer, in particular, had reduced their inventions to practice before Pallin did, Pallin broadened his patent, correctly or incorrectly, to include the incisions of Singer and McFarland. This is not an uncommon strategy for a first inventor and patentholder to execute against alleged infringers. However, Pallin’s strategy backfired because it turned out that he was not the first to invent a sutureless incision. Thus, he subsequently executed a strategy of narrowly interpreting the scope of his patent in order to set his incision apart from others’ incisions, and consequently to maintain the integrity of his patent.

In his efforts to distinguish the chevron incision from the incisions of others, Pallin touted the unique components and supposed advantages of his incision, but many of these, whether real or not, were not specified in his patent. One of the supposedly unique components of the chevron incision was a tunnel length to width ratio greater than one, and one of the supposed advantages was that the chevron incision

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<sup>69</sup> June 1994 deposition as an expert witness. In saying “an inverted V,” counsel is referring to the shape of the chevron and not to Gills’ incision. Pallin II deposition, p. 74 in Defendants’ Reply Memorandum in Support of Their Motion for Summary Judgment (filed 1/4/95), p. 14.

<sup>70</sup> Defendants’ Reply Memorandum in Support of Their Motion for Summary Judgment (filed 1/4/95), p. 15.



could admit foldable and non-foldable lenses. As mentioned previously, whether the patent allowed suture use or not was also at issue. The defense was unimpressed:

“What the claims do not define include: making a scleral tunnel having any particular length-to-width ratio, making a scleral tunnel that widens as it progresses toward the anterior chamber, making a scleral tunnel with a stretchable outer opening in the sclera, making an incision limited by the type of lens inserted into the patient, or making a scleral incision that must be “sutureless” under all circumstances. Regarding the last point, it is absolutely clear that the patent itself (see col. 4, lines 41 to 45) teaches that a suture can be used, particularly for large diameter lenses of “up to 6 millimeters in diameter.”<sup>71</sup>

Without inclusion in the claims of a patent, the supposedly unique components and advantages could not unequivocally serve as elements of infringement or of anticipation.

The defense took close aim at Pallin’s statement that a particular tunnel length to width ratio was required for self-sealing. The defense wrote, “Regarding the newly-asserted, allegedly crucial, length-to-width relationship of the tunnel, **the Pallin patent is totally silent.**” (Original emphasis)<sup>72</sup> Because the Pallin patent did not teach the dimensional relationship, the defense found it curious that the plaintiff wanted the work of McFarland, Gills, and Singer discarded as prior art because this work did not use Pallin’s tunnel dimensions. The defense noted that in March 1990 Singer constructed a scleral tunnel that widened as it coursed from the scleral incision to the anterior chamber of the eye, which is the extent of what the Pallin patent dictates regarding tunnel construction.<sup>73</sup>

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<sup>71</sup> Defendants’ Reply Memorandum in Support of Their Motion for Summary Judgment (filed 1/4/95), p. 6, Footnote 4.

<sup>72</sup> Defendants’ Reply Memorandum in Support of Their Motion for Summary Judgment (filed 1/4/95), p. 16.

<sup>73</sup> See claim 29 of the Pallin patent and Exhibit B of Singer’s article, entitled “Frown incision for minimizing induced astigmatism after small incision cataract surgery with rigid optic intraocular lens implantation,” in the 1991 Supplement to the *Journal of Cataract and Refractive Surgery*.





But most damaging was the defense's calculation that even Pallin's teaching did not fulfill the critical dimensional relationship of the scleral tunnel. Using carefully selected values for incision distance and lens diameter, the defense showed that there are some situations in which doing what is taught in the Pallin patent does not yield the desired tunnel length to width ratio:

"On this point, Pallin is inconsistent. He criticizes the earliest incisions of Drs. McFarland and Gills as being too far posterior to the limbus, yet such locations are ones that would produce the supposedly critical relationship, a tunnel length greater than or equal to its width. The Pallin patent itself is also internally inconsistent with the now-asserted crucial ratio. It teaches starting an incision 1.5 to 3.0 mm posterior to the limbus and having a variable width. It provides no guidance as to how these two factors relate, if at all. It states that one can insert lenses having a width "up to 6.0 mm". Taking the Pallin patent at face value, one could make an incision 1.5 mm posterior to the limbus and wide enough to pass a 6.0 mm diameter lens. This particular combination, and many others that are within the literal wording of the patent specification and claims, will result in a tunnel whose width exceeds its length – the opposite of what Pallin now says is critical to form a self sealing incision. Certainly, Pallin did not contemplate nor teach this critical limitation as part of his invention. Nor do the Pallin patent drawings support Pallin's recent argument. As drawn, they show a tunnel whose length is less than its width."<sup>74</sup> (See Figure 2)

Whether or not the critical tunnel dimensional ratio was responsible for the self-sealing of the chevron incision, the range of values for incision distance and lens diameter could theoretically yield combinations



for which the tunnel dimensional ratio was not achieved. Furthermore the defense drew a distinction between Pallin's claims of tunnel dimensional ratio and what is stated in the patent regarding mechanism of tunnel closure (See Figure 4 for "Pallin's Invention and Patent"):

"In his patent Pallin states that sealing occurs because of "force vectors acting on incisions 22a and 22b [the chevron]," once the eye is inflated. Col 4, lines 13-15. In other words, the seal is at the outer scleral line of incision. In his deposition testimony (cited in Defendants' original motion papers) and in his Opposition, Pallin asserts that sealing occurs within the tunnel and, therefore, the shape of the tunnel is critical."<sup>75</sup>

It is possible that the force vectors acting on the scleral lines of the incision also act in the tunnel, but the defense's reading of the patent is reasonable. The defense then pointed out that substantially the rest of the ophthalmologic community including Ernest and Singer believed the corneal lip made for safe self-sealing. However, the defense pointed out that why sealing occurs was not an issue for summary judgment. What was at issue was that a certain result should be achieved if the steps contained in Pallin's patent are followed.

This thought provided a mental backdrop to the defense's view of the issue of how to define "substantially self-sealing." While the issue of definition seemed unresolvable with the plaintiff asserting that the invention is a *sutureless* incision and the defendant asserting that Pallin's patent teaches that a suture can be used, the defense described Pallin's inconsistent thinking on the issue:

"Pallin testified that the term "substantially self-sealing" includes the situation where there is a wide incision for large diameter optics and the incision may not seal "completely". This is one Pallin

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<sup>74</sup> Defendants' Reply Memorandum in Support of Their Motion for Summary Judgment (filed 1/4/95), p. 17, Footnote 18.



interpretation. It certainly is consistent with a specification that discusses the use of sutures for large incisions. Using completely circular reasoning, Pallin also testified that, if a wound self-seals perfectly, the incision infringes his patent and, if it does not, the incision does not infringe. At another point, he testified that “substantially” means sealing most of the time, or it refers to the period of time during a cataract operation before the eye is inflated. However, to assess prior art and infringement, one does not have to know or adopt any of these definitions which are external to the patent specification. The court need only look at what steps the patent claims **require** one to perform to come within the asserted claims.”<sup>76</sup>

In the end, the defense’s analysis of Pallin’s patent claims and testimony weakened Pallin’s position and further forced him to narrow the scope of his patent. But the legal volleys between Pallin and the defendants would end to Pallin’s advantage.

### Exposing Two Achilles Heels

On May 1, 1995, almost two years after Pallin filed a Complaint alleging patent infringement, Judge Billings closed the second phase of the case. In his Opinion and Order, he wrote that a U.S. patent is presumed valid and can be invalidated only with clear and convincing evidence.<sup>77</sup> He also wrote that the Court can grant summary judgment if no genuine issue as to material fact exists. Judge Billings found “complex factual disputes” in the case at hand and rejected the defense’s motion for summary judgment, listing three disputed issues:

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<sup>75</sup> Defendants’ Reply Memorandum in Support of Their Motion for Summary Judgment (filed 1/4/95), p. 19.

<sup>76</sup> Defendants’ Reply Memorandum in Support of Their Motion for Summary Judgment (filed 1/4/95), p. 20, Footnote 20.

<sup>77</sup> Cites 35 U.S.C. Section 282. Opinion and Order (filed 5/1/95), p. 6.



“Our comparison of the surgical techniques practiced by Drs. McFarland, Gills and Singer with the asserted claims of the ‘111 patent reveals that genuine issues of material fact exist as to whether the works of any one of these doctors fully anticipated Plaintiff’s claims. Taking the evidence in the light most favorable to the Plaintiff, we find that complex disputes exist as to the following issues: whether Dr. McFarland’s straight line incision and vertical cuts fall within the ambit of Plaintiff’s claims; whether the distance from the limbus of the incisions made by Dr. Gills during the March 1990 surgeries falls within the 1.5 to 3.0 millimeter range advocated by Plaintiff’s patent; and whether the incision made by Dr. Singer in his March 1990 surgery was capable of self-sealing. Accordingly, Defendants are not entitled to summary judgment.”<sup>78</sup>

Billings acknowledged that Gills’ inverted V incision would have anticipated the chevron incision if it were in the range claimed by Pallin, but stated that Gills’ deposition statement that he “guesstimated” distances did not show proof of anticipation. He seemed to accept the argument that Pallin’s invention was obvious in light of primary considerations of nonobviousness,<sup>79</sup> but he wrote that the defense did not demonstrate that factual disputes did not exist with respect to secondary considerations of nonobviousness - the *John Deere* considerations.

Had the defense shown that Gills’ incision distances fell within Pallin’s range or that Pallin’s invention was also obvious with respect to secondary considerations, summary judgment would have been granted to the defense and Pallin’s patent would have been invalidated. Now, however, the parties were destined to fight a legal battle in a jury trial. But the defense had one more spear to throw.

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<sup>78</sup> Opinion and Order (filed 5/1/95), p. 8.

<sup>79</sup> This involves determining the scope and content of the prior art, differences between the prior art and the claims at issue, and the level of ordinary skill in the pertinent art.





After denying summary judgment, Judge Billings reassigned the case to Judge William K. Sessions III, another U.S. District Judge. Judge Billings then retired. A settlement conference with Judge Sessions was scheduled for November 1995 at which time a trial date could be set, if necessary.<sup>80</sup>

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<sup>80</sup> The settlement conference was originally scheduled for 9:30 am on Tuesday, November 7, 1995, but the defense moved for a continuance because many of the counsel had major commitments. One of the defense counsel had open heart surgery. The defense also noted that it would be difficult to have ophthalmologists witnesses travel to court (Burlington, VT) without adequate lead time. The plaintiff agreed to the continuance.



## X. Professional society involvement

Pallin's lawsuit against Singer was received negatively by the medical profession and some members of Congress. It provoked deep emotion and outrage in some quarters where it was seen as inconsistent with medical tradition and good ethics. Pallin had few allies, if any, in the medical profession. The American Medical Association (AMA) took the lead in commenting on the issues raised by *Pallin v. Singer*, but its seemingly inconsistent position on patenting medical inventions strained its credibility. Much of the discussion in the medical community was echoed on Capitol Hill in the fall of 1995 as Congress considered banning medical method patents. The public debate over patenting medical procedures was as much about ethics as it was about economics. This chapter recounts elements of the public debate over *Pallin v. Singer* and examines the AMA's historical and contemporary position on patenting in medicine.

### Reacting with Outrage

Spurred primarily by Pallin's infringement suit against Singer but also by other efforts to enforce medical procedure patents, the American Medical Association (AMA) and other medical specialty societies condemned the trend of increasing patenting of medical and surgical procedures.<sup>1</sup> The AMA House of Delegates issued a preliminary statement in 1994 and asked the AMA Council on Ethical and Judicial Affairs (CEJA) to examine the issue. The House of Delegates issued another condemning statement on June 18, 1995 which advocated that the AMA work with Congress to legislatively prohibit the patenting of medical procedures.<sup>2</sup> AMA President, Robert McAfee, stated that the "mere thought that a procedure would be secretive or that someone would try to profit from it is. . . abhorrent to most physicians and surgeons."<sup>3</sup> McAfee further pointed out that leading surgeons, such as Allen Whipple and William Halstead who developed methods for pancreatic surgery and radical mastectomy respectively, did not

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<sup>1</sup> The medical specialty societies included among others the American Society for Cataract and Refractive Surgery, the American Institute of Ultrasound in Medicine, and the American Urological Association.

<sup>2</sup> "AMA: Annual Meeting Statement Criticizes Surgical Patents," *Health Line*, June 20, 1995; Mossinghoff, G. "Remedies Under Patents on Medical and Surgical Procedures," *Journal of the Patent and Trademark Office Society*, November 1996, p. 790.



attempt to patent their work. In the summer of 1995, the AMA co-sponsored a medical procedure patent briefing for Congress, in which Singer participated as a panelist.<sup>4</sup>

Many physicians did not take kindly to Pallin's lawsuit. In an editorial, Dr. William Morain, a microvascular surgeon, condemned the "entrepreneurial aggressiveness" of Pallin over "a few millimeters worth of surgical incision."<sup>5</sup> Dr. John Glasson, Chair of the AMA Council on Ethical and Judicial Affairs, asked, "How can anyone claim to own the way one turns one's knife when performing surgery?"<sup>6</sup> Dr. Gary Leifer, President of the Kansas Urological Society, who had been combating the enforcement of another medical method patent (penile drug injection method for treating impotence) by Men's Health Resources, Inc. disapproved of patents on medical procedures as a matter of principle.<sup>7</sup> Alluding to *Pallin v. Singer*, he lamented what he saw as the medical profession's abandonment of Hippocratic ideals. Citing an "unholy alliance between a few doctors and lawyers" as the most recent threat to the medical profession, one physician deplored Pallin's lawsuit against Singer saying that patenting medical thought processes and surgical techniques runs against medical tradition.<sup>8</sup> One physician-editor urged his colleagues to "put a stop to this insanity" of patenting surgical procedures.<sup>9</sup> However, he noted that surgeons were patenting methods in order to avoid being left out of any financial windfall that might come to companies which commercialized new methods. He worried that this trend would lead to less publication of surgical methods and increased health care costs. In November 1993, the Committee on Ethics of the American College of Obstetricians and Gynecologists issued an opinion against patenting medical procedures and cautioned physicians to recognize the ways in which incentives to increase income threatened patient

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<sup>3</sup> Squires, S. "AMA Condemns Patents For Medical Procedures," *The Washington Post*, June 20, 1995, p. A01.

<sup>4</sup> Coble, Y.; Ile, M.; and Taylor, M. "Patenting of Pure Surgical and Other Medical Procedures / Medical Community's Response and Need for a Legislative Solution," *Journal of the Florida Medical Association*, May 1996, p. 331.

<sup>5</sup> Morain does not refer to Pallin by name. Morain, W. "Patently Unethical," *Annals of Plastic Surgery*, March 1996, p. 334.

<sup>6</sup> Quoted in Chartrand, S. "Why Is This Surgeon Suing?" *New York Times*, June 8, 1995, p. D-1.

<sup>7</sup> Leifer, G. "The Latorre Patent Issue: Extortion or Entrepreneurship," *Urology*, May 1995.

<sup>8</sup> Rakatansky, H. "Patenting Medical Thoughts," *Rhode Island Medicine*, May 1995, p. 128.

<sup>9</sup> Habal, M. "Patents for Surgical Procedures: A New System Comes of Age," *Journal of Craniofacial Surgery*, January 1996, p. 1.



care.<sup>10</sup> Dr. Thomas Starzl, the first surgeon to successfully perform a liver transplant, worried that the patient population would be “converted to an animal farm because of the economic interest in controlling” medical methods.<sup>11</sup>

However, some people defended Pallin, or at least defended the patent system. One ophthalmologist who holds method patents for laser technology defended patents because, in his view, they encourage innovation in our free-market society.<sup>12</sup> Dr. Peter Wilk, a Manhattan surgeon with 140 patents, found it inconsistent that the medical community opposed patents on free-standing methods but did not object to patents on methods which are integral to a device.<sup>13</sup> Dr. R. Arnold Smith, a Mississippi oncologist with patents on cancer therapy combinations, rejected the notion of medical methods as community property: “that’s a socialist concept. That’s not the general policy of the rest of the country, so why apply it to medicine? Vested interests like property rights are what spur progress.”<sup>14</sup> Responding to a *Los Angeles Times* article which he believed portrayed Pallin and other surgeons who seek procedure patents as “bad,” patent attorney Paul Hunt stated that patents can further the public good by reducing health care costs. In his view, the possibility that Pallin may not have been the first to perform a sutureless incision did not justify banning patent protection for all surgical methods.<sup>15</sup>

The American Society of Cataract and Refractive Surgery (ASCRS) and other medical organizations released a white paper in May 1995 which called for a legislative ban on patents for medical and surgical procedures.<sup>16</sup> Representative Ron Wyden (D-OR), who co-introduced a bill to ban medical procedure patents in March 1995, remarked, “It is really outrageous to think that one individual would get 17 years of patent protection for a procedure which most of the time a very large number of colleagues had

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<sup>10</sup> American College of Obstetricians and Gynecologists, Committee on Ethics, “Commercial ventures in medicine: concerns about the patenting of procedures,” *International Journal of Gynecology and Obstetrics*, January 1994, p. 87.

<sup>11</sup> Quoted in “Bill Would Stop Method Patents: Urologists Give Bill Strong Support,” *Urology Times*, Sept. 18, 1995.

<sup>12</sup> Lowes, R. “Are you stealing from other doctors? Medical procedure and method patents,” *73 Medical Economics*, March 11, 1996, p. 195.

<sup>13</sup> Quoted in Chartrand, S. “Why Is This Surgeon Suing?” *New York Times*, June 8, 1995, p. D-1.

<sup>14</sup> Quoted in Chartrand, S. “Why Is This Surgeon Suing?” *New York Times*, June 8, 1995, p. D-1.

<sup>15</sup> Hunt responds to article by Neergaard, L in the *Los Angeles Times* (See bibliography). Hunt, P. “Many Arguments Support Continued Patent Protection for Surgical Procedures, Attorney Says,” *PR Newswire*, April 3, 1995.





a hand in developing. . . It really comes down to whether you want to call medicine a science or a just a garden-variety business.”<sup>17</sup> Wyden also expressed concern that patenting medical procedures would increase health care costs with “road tolls for procedures.”<sup>18</sup>

A day after the AMA House of Delegates released its June 1995 statement, the AMA Council on Ethical and Judicial Affairs (CEJA) released its report on the patenting of medical procedures. CEJA concluded that it is unethical for physicians to obtain and enforce patents on medical procedures. Dr. John Glasson, Chair of CEJA, stated, “Since the time of Hippocrates, physicians have relied on the open exchange of information without expectation of financial reward for advancing medical science. Patenting of medical procedures would significantly detract from mutual trust and respect for the patient/physician relationship.”<sup>19</sup> However, Pallin and other commentators -- mostly patent attorneys -- pointed out that the medical profession was inconsistent in its stance toward patenting medical inventions.<sup>20</sup> The AMA allowed physicians to patent medical products, such as drugs and devices, but did not allow physicians to patent medical procedures. Pallin called this a “dubious distinction at best.”<sup>21</sup>

### Going Public

Meanwhile, the participants in *Pallin v. Singer* contributed to the public debate. Pallin stated that he pursued a patent more for peer recognition than for financial profit, and added that he believed he was operating within the existing system.<sup>22</sup> On June 17, 1995, Pallin appeared on National Public Radio’s program “All Things Considered,” where he debated George Annas, Chair of the Health Law Department

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<sup>16</sup> White Paper: “Patents for Surgical/Medical Procedures, A Call for Legislative Prohibition,” May 1995. Issued by Jenner & Block (law firm).

<sup>17</sup> Squires, p. A01.

<sup>18</sup> Bowman, L. “Physicians stake claims to their art of healing; Courts will rule on patents, while medical societies denounce them as unethical, harmful,” *The San Francisco Examiner*, July 16, 1995, p. B-1.

<sup>19</sup> “AMA: Annual Meeting Statement Criticizes Surgical Patents,” *Health Line*, June 20, 1995.

<sup>20</sup> Neergaard, L. “Move to Patent Surgical Procedures Sparks Fight; Royalties: Doctors Say Controlling the Way They Practice Medicine in Such a Way is Unethical and Drives Up Health Care Costs. They’ve Persuaded Congress to Consider Outlawing the Practice,” *Los Angeles Times*, April 2, 1995.

<sup>21</sup> Pallin, S. “Patents spread new ideas,” *USA Today*, June 19, 1995, p. 10A.

<sup>22</sup> Stating that medicine “is a capitalist endeavor,” Pallin says he would charge a \$5 royalty on the \$1,000 procedure of cataract surgery. Using Singer’s estimates of 1.35 million cataract surgeries, 45% of which use a frown-style incision, this leads to royalty revenue of over \$3 million. Bowman, p. B-1.



at Boston University Medical School.<sup>23</sup> Pallin defended his decision to obtain a patent. He portrayed the patent system as a way to preserve incentives for physicians to develop new techniques in a managed care environment. Annas conceded that it was reasonable to turn to the patent system in the business ethos of industry, but in the patient ethos of medicine, he believed patents would hurt patients and the profession. Of the Patent and Trademark Office, Annas said:

“the last people you want to be making the decision about [whether a technique is patentable or not] are the people in the Patent Office. They have no interest or experience in the practice of medicine....They’re not in the business of public policy, medical ethics or the practice of medicine.”

On the same day the CEJA released its report on the patenting of medical procedures, Pallin published a short piece, entitled “Patents spread new ideas,” in *USA Today*.<sup>24</sup> Pallin wrote that procedure patents were proliferating because computerized records had now made it possible to monitor the use of intellectual property in medicine. In his view, “like climbing Mount Everest, physician/inventors will take advantage of patent protection for intellectual property because it is there.” Citing the U.S. Constitution and *The Federalist Papers*, Pallin declared that Congress had the ability to confer, but not to refuse, patent protection. Pallin expressed concern that banning medical procedure patents would constitute inequality under the law as medical procedures and non-medical procedures would be treated differently under patent law. In Pallin’s view, “Patents exists solely for the purpose of encouraging rapid dissemination of new ideas.” Finally, Pallin asked if the AMA’s position was based on ethics or economics, and then told the AMA to “chill out.”

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<sup>23</sup> Zwerdling, D. “Controversial Patent Issued for Medical Procedure,” (Transcript) “All Things Considered” (National Public Radio program). June 17, 1995.

<sup>24</sup> Pallin, S. “Patents spread new ideas,” *USA Today*, June 19, 1995, p. 10A.



Singer publicly stated that he had developed and published his cataract surgery incision months before Pallin's patent was issued.<sup>25</sup> He also wrote an article entitled "The Free Exchange of Medical and Surgical Knowledge" in which he developed a framework to describe the exchange of ideas in medicine.<sup>26</sup> Singer believed medical method patents would slow the development of techniques. He advocated legislative action and also solicited contributions for his legal defense fund. Peter Manus, one of Singer's attorney, added to the public debate when he said that method patents would "put chunks of medical knowledge in the hands of for-profit institutions piece by piece."<sup>27</sup> Robert Portman, another of Singer's attorneys, stated that *Pallin v. Singer* signaled the prospect of medical procedure patent proliferation and represented "the potential havoc that medical procedure patents can wreak on the delivery of medical services."<sup>28</sup>

In a medical journal article, James Longacre, Pallin's attorney, touted the virtues of patents and downplayed the alleged problems of medical method patents.<sup>29</sup> He wrote that, to his knowledge, of approximately 100 surgical method patents, only one was currently being infringed. Longacre stated that method patents for surgical procedures would have an "inconsequential effect" on health care costs because royalties on them make up a small component of a patient's medical bill. He believed these royalties were justified because they were no different than royalties for devices and drugs. Longacre believed opposition to medical method patenting stemmed from physicians' unfamiliarity with patents and would only decrease with the corporatization of medicine:

"Ten years from now most surgeons may be employees of enormous or impersonal corporations. Will there be any objection to suing corporations for infringement of a method patent?....As in other

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<sup>25</sup> Squires, p. A01.

<sup>26</sup> Singer, J. "The Free Exchange of Medical and Surgical Knowledge." Revised January 1996. Presentation at the ASCRS Symposium on Cataract, IOL, and Refractive Surgery on April 10, 1994 in Boston, MA. Singer also wrote a pamphlet (based on his presentation) which solicited contributions for his legal defense.

<sup>27</sup> Bowman, p. B-1.

<sup>28</sup> Portman, R. "Patenting Medical and Surgical Procedures Is Threatening Medical Progress," *Policy Options*, May 1996, p. 32.



professions, there is often resistance in medicine to new and unfamiliar concepts. Indeed, the history of medicine is replete with struggle against reactionary attitudes. The danger of method patents is illusory, and the advantages of their use have not been fully considered.”<sup>30</sup>

However, in the same journal issue, in response to Longacre, two authors wrote that physicians have an ethical duty to care for patients regardless of the source of treatment knowledge.<sup>31</sup> They also believed that changes in the marketplace would compromise patient care only if physicians allowed it.

#### Rendering Opinion: the CEJA Report

The CEJA report was one of few in-depth statements on patenting medical methods written by a medical society.<sup>32</sup> CEJA appeared to be trying to prove, in any way possible, its desired conclusion of the unpatentability of medical procedures, even though it stated that “there is arguably a role for medical process patents similar to that of ethically acceptable patents on devices and pharmaceuticals.”<sup>33</sup> What Pallin called the “dubious distinction” between products and procedures in the context of patentability made achieving CEJA’s apparent objective difficult, if not impossible. Pallin believed CEJA’s opinion “would not hold up in a high school debate society.”<sup>34</sup>

CEJA rejected one of the standard arguments in support of patents – to encourage innovators to pursue invention – and doubted that prohibiting medical method patents would curb innovation in procedures. Seeing no “practical, principled basis for distinguishing appropriate and inappropriate medical process patents” CEJA concluded that regulation could not address ethical problems with procedure patents

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<sup>29</sup> Longacre, J. “Issues and Debate / The Usefulness of Method Patents for Surgical Procedures,” *Annals of Vascular Surgery*, Vol. 10, No. 1, 1996, pp. 1-2.

<sup>30</sup> Longacre, p. 2.

<sup>31</sup> Rosenberg, R. and Gewertz, B. “Issues and Debate / The Usefulness of Method Patents for Surgical Procedures,” *Annals of Vascular Surgery*, Vol. 10, No. 1, 1996, pp. 2-3.

<sup>32</sup> Report 1 of the Council on Ethical and Judicial Affairs (A-95), “Patenting of Medical Procedures (Informational Report),” Executive Summary. The ASCRS helped develop an in-depth White Paper entitled “Patents for Surgical/Medical Procedures, A Call for Legislative Prohibition,” May 1995. Issued by Jenner & Block (law firm). The CEJA report and other medical society position statements built similar ethical and political positions with essentially the same arguments.

<sup>33</sup> “Patenting of Medical Procedures,” Executive Summary.





and therefore believed that doctors should not obtain or enforce medical procedure patents.<sup>35</sup> As Pallin pointed out, many of the arguments forwarded against the patenting of medical procedures could also be forwarded against the patenting of medical products. Furthermore, CEJA did not address method-of-use patents, which are a hybrid of product and method patents. The bottom line of CEJA's opinion seemed to be an economic justification of an ethical position against the patenting of medical procedures.

In discussing ethical concerns surrounding the patenting of medical procedures, CEJA built an argument construct which yields its desired outcome. The construct does not allow broad consideration of patent law across all industries, and it defies logic and fairness by allowing the uneven application of arguments to product and process patents. In sum, CEJA starts with argument by precedent, then creates a fail-safe by resorting to a different line of thinking, and subsequently tries to make a dubious distinction between product and process patents. Looking to precedent, CEJA noted that the AMA Principles of Medical Ethics and Code of Medical Ethics state that physicians should share knowledge and techniques freely and should not withhold for personal gain. However, as Pallin repeatedly pointed out, if these principles of ethics imply prohibition of patents on medical procedures, then they should imply prohibition of patents on medical products. CEJA anticipated this criticism and acknowledged that the AMA's principles could be interpreted to be both consistent and inconsistent with patenting procedures. CEJA acknowledged that because patents require full disclosure of an invention (implying no withholding), they could be consistent with the AMA's ethics of sharing knowledge.

Realizing that its argument by precedent was tenuous at best, CEJA turned to a different line of thinking by stating that even if medical procedure patents were consistent with AMA principles, they reduce professionalism:

"The patenting of medical procedures, with its emphasis on individual reward, selective sharing and ownership, undermines the coherence of the profession. . . . One of the fundamental principles in medicine is that the health of the patient is a physician's most basic concern. Much

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<sup>34</sup> Pallin interview, p. 14.



of the respect and trust accorded patients arises from the perception that economic concerns do not generally impact medical decisionmaking. In opposition, medical process patents are committed to the primacy of economic benefit and reward. To the extent which economic goals are elevated above those of patient health, the integrity of the profession is severely weakened.”<sup>36</sup>

However, as Donald Dunner, Chair of the Section of Intellectual Property Law of the American Bar Association, stated later in a Congressional hearing on medical method patenting, economic concerns are a part of medical decisionmaking.<sup>37</sup> One might imagine an HMO that confines antibiotic choices to a restricted formulary or a gynecologist who performs unnecessary hysterectomies because of favorable reimbursement. However, CEJA’s point is well-taken in that procedure patents might alter patient perceptions that economics do not affect medical decisionmaking. But, CEJA made no comment about the effects of product patents on the medical profession. Do product patents not also possess “emphasis on individual reward” and “selective sharing and ownership” with a commitment to “the primacy of economic benefit and reward”?

In CEJA’s view, there are “compelling reasons” to distinguish between medical product patents and medical procedure patents.”<sup>38</sup> CEJA identified restricted access to patented procedures, increased financial burden to patients, and potential breach of patient confidentiality as concerns which distinguish product and process patents. CEJA believes clinical access will be restricted for three reasons. First, a procedure may be unavailable due to high royalty price or limited licenses. Second, a physician might rationalize an inferior treatment alternative because he does not want to purchase a license or refer to a physician that owns a license. Third, a physician may not know if a new procedure is patented and may therefore choose not to use it because he does not want to be the potential target of a lawsuit. The first two reasons can easily be applied to product patents. The price of a product, patented or not, may render it

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<sup>35</sup> “Patenting of Medical Procedures,” Executive Summary.

<sup>36</sup> “Patenting of Medical Procedures,” p. 3.

<sup>37</sup> Hearing, p. 82, 89.



inaccessible to those who cannot afford it. For the second reason, a physician may choose, for instance, to prescribe an inferior drug because his office receives wholesale discounts on the drug or because it would be cheaper for the patient.<sup>39</sup> Pallin rejected the argument that physicians would fail to select the most effective method because they have to pay a royalty or purchase a license. He said physicians are bound to do their best for patients.<sup>40</sup> The third reason for restricted clinical access derives from the fact that licensing fees are incorporated into the price of products, whereas licensing fees are external to methods. The threat of a patent infringement suit does not exist with purchasing a medical product because the patent licensing fee is built into the product. This is not the case with patented procedures. In CEJA's view, there is no obvious way of knowing if a procedure is patented. This last reason bears some merit but perhaps only in the short-term. Word-of-mouth and a listing of patented procedures (perhaps compiled by a medical society) should remedy this problem. Also, the cost of litigation is high. Thus, patentholders would first send cease-and-desist letters and try to negotiate a settlement.

CEJA also raised the issue of restricted access of procedures for academic purposes, but it offered a sensible solution. In CEJA's view, unsafe and low-quality procedures might achieve widespread use because peer review would not occur unless peers paid licensing fees to use patented procedures in clinical assessment. However, CEJA correctly pointed out that the use of a patented product or procedure for experimental or research purposes does not constitute infringement.

CEJA expressed concern that disclosure of procedures would take longer when procedures are patented than when altruism and science motivate innovation.<sup>41</sup> CEJA stated that even full disclosure via a patent does not constitute availability for a physician in that he may now know of a technique in detail, but he cannot use it. Once again, CEJA did not apply its thinking to product patents where the same arguments would apply. Also, its view that altruism and science motivate innovation would appear naïve.

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<sup>38</sup> "Patenting of Medical Procedures," p. 3.

<sup>39</sup> Furthermore, this physician may not refer the patient to a colleague who would prescribe the best drug for lack of a desire to lose patient fees. Alternatively, an office-based physician may choose to perform, and bill for, an ultrasound in his office when it would have been clinically more effective to immediately refer the patient to an imaging center for a computed tomography (CT) scan. (The office-based physician is assumed not to own a CT scanner, which is a patented device.)

<sup>40</sup> Hearing, p. 41.

<sup>41</sup> "Patenting of Medical Procedures," p. 4.



CEJA recognized that patents may be needed to encourage some physicians to disclose their inventions. CEJA offered the fact that four generations of the Chamberlen family concealed their use of the obstetrics forceps, and it conceded that subtle forms of non-disclosure occur today. It noted that free exchange of information “may not be blocked by patenting any more than it is by concerns about dominance in a field, tenure, and prestige” and acknowledged that the medical community “tolerated” barriers of geography and financial means in patient access to treatment.<sup>42</sup> However, it opposed creating additional barriers to data sharing and clinical access.<sup>43</sup> Pallin later testified before Congress, “aside from the historical oddity of the obstetrical forceps case, there is no evidence whatsoever that new discoveries have been restricted. To the contrary, the system is working well. It’s not broken. Let us not try to fix it.”<sup>44</sup>

While CEJA noted that patenting by an academic institution might lead to royalties that would support further research, it believes that patenting as a mechanism of encouraging disclosure is unjustified because it is solving a problem that should not exist, and it is rewarding poor ethics:

“Given the aforementioned strong ethical prohibitions on withholding information, patenting is being inappropriately promoted to solve a dilemma that clearly should not exist. While those who violate disclosure requirements may respond to economic incentives rather than principles, it is inappropriate to reward their unethical behavior by providing an economic benefit to disclosure. Rather patenting can be ethically defensible only if it performs a function beyond merely rewarding violators for something they should have done in the first place.”<sup>45</sup>

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<sup>42</sup> “Patenting of Medical Procedures,” p. 5.

<sup>43</sup> “Patenting of Medical Procedures,” p. 5.

<sup>44</sup> Hearing, p. 41.

<sup>45</sup> “Patenting of Medical Procedures,” p. 7.





But CEJA did not offer an alternative mechanism to prevent non-disclosure, and it did not apply this line of thinking to product patents. Should its ethical argument fail to convince, CEJA also dismissed the notion that patents provide incentive to innovate by stating that no empirical grounds for it exist, pointing to the rapid advance of medicine after World War II in spite of few patents issued for procedures. However, one could argue that increased research funding fueled the rapid advance of medicine, and the natural sciences as a whole, after World War II.

CEJA believed procedure patent royalties would increase health care costs. In Pallin's view, some patents would increase health care costs but other patents, like his, would reduce costs.<sup>46</sup> CEJA offered no empirical evidence for its belief but demanded empirical evidence for the opposing viewpoint:

“While in certain cases patenting may be fiscally neutral or actually economically benefit patients by leading to a decrease in the cost of treatment as new, less expensive procedures replace older ones, it is not clear to what extent this line of reasoning is generalizable, and there is no supporting empirical data from which to draw conclusions.”<sup>47</sup>

And, once again, CEJA did not apply its line of thinking to product patents. Pallin put CEJA's concern in perspective:

“Royalties on drugs and devices will always contribute to the cost of care far more dramatically than a few medical methods. And no one suggests that new expensive drugs or diagnostic procedures should be discouraged. So why discourage innovations in medical procedures...?”<sup>48</sup>

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<sup>46</sup> Hearing, p. 41.

<sup>47</sup> “Patenting of Medical Procedures,” p. 6.

<sup>48</sup> Hearing, p. 41.



CEJA asserted that patenting medical procedures might lead to breaches of patient confidentiality. Monitoring the use of a medical procedure, which typically occurs behind closed doors in an exam room or an operating room, is difficult. Practically speaking, monitoring would require access to patient records which would presumably be given to someone not involved in the direct care of the patient. CEJA proposed that doctors and hospitals pay a licensing fee based on the number of patients examined rather than by the number of actual patented procedures used. This is a reasonable starting proposal, but it may not be supported by all parties.

CEJA continued to navigate the narrow, if not non-existent, space between developing a sensible rationale for its position and countering criticisms of its position. The patent on surrogate embryo transfer (SET) constitutes perhaps one of the strongest arguments of CEJA's critics because CEJA deems the SET procedure to be "appropriately" patentable. Although CEJA rejects the standard rationale (incentive to innovate) for patents, it recognized that in order to develop methods, such as SET whose development costs CEJA reported as ranging from \$500,000 to \$1.25 million,<sup>49</sup> patents may be needed to attract private R&D funding. Dr. William Noonan, an ophthalmologist and patent attorney who has written on patenting in medicine and biotechnology, believes that pure procedures are usually developed in the course of clinical practice and that exceptions like SET are unusual.<sup>50</sup> Clearly alluding to *Pallin v. Singer*, Dr. Charles Kelman, inventor of phacoemulsification and the president of the ASCRS, declared to Congress, "An improved way of making that incision does not require funding from venture capitalists."<sup>51</sup>

CEJA argued that the level of funding needed for procedure patents is less than that for products. Anticipating a key criticism of its remarks, CEJA acknowledged SET as a counterexample to its statements and tried to absolve itself of inconsistency:

"SET is one obvious counterexample, yet this alone does not  
undermine a prohibition on patenting of medical procedures as we do

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<sup>49</sup> "Patenting of Medical Procedures," p. 6, Footnote 29.

<sup>50</sup> Hearing, p. 65.

<sup>51</sup> Hearing, p. 70.



not, in any context, require general rules to meet the impossible condition of working faultlessly.”<sup>52</sup>

Although CEJA thinks SET is an appropriate candidate for patenting, it noted that SET is a rare procedure (unlike breast tumor detection) and has relatively less effect on physician autonomy. CEJA advocates a rule which would deny protection to a procedure it considers worthy of a patent. It would seem that level of R&D expenditure and not the distinction between products and procedures is what CEJA should have addressed. Perhaps it feared portraying itself as concerned with economics more than ethics. It alluded to ethics as an additional criterion of patentability, but offered no explicit ethical screening criteria.

Towards the end of its report, CEJA explained its distinction between patenting medical products and patenting medical procedures:

“The appeal to non-financial incentives does not entirely address the issue of incentive for innovation, for internal recognition and respect do not necessarily generate the money to enable the creation of new procedures in the first place. The patent system provides incentive for investors as well as individual physician-inventors, and the investors are neither recipients of nor concerned with internal prestige as much as financial reward. Yet this defense of medical process patents is ultimately unconvincing. While there is no substantive empirical data about the level of incentive needed to promote innovation and disclosure in the biomedical sciences, it is reasonable to claim that this level would be significantly lower for procedures than it would be for devices and pharmaceuticals. Unlike the development of innovative medical instruments or pharmaceuticals, the development of medical processes usually relies on intellectual curiosity and creativity rather

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<sup>52</sup> “Patenting of Medical Procedures,” p. 8.



than the availability of capital for research and development. Especially in the case of pure medical process patents, the innovative step tends to be a novel mental step rather than the creation of a new physical entity. While this does not mean that this type of innovation is any less worthy of reward, it does imply that the need for outside funding costs that might require later recovery is generally less pressing than in the case of devices or pharmaceuticals.”<sup>53</sup>

While it is reasonable to believe that investors are more concerned with financial reward than prestige, the same might be said of some physicians. The notion that the level of incentive needed is less for procedures than for products might be true when considering all products and all procedures at one point in time. However, if procedures like SET come to comprise a greater portion of medical invention (on a financial or volume basis), CEJA’s assumption would have to change. Furthermore, individual inventions may constitute exceptions. Finally, the nature of developing products and procedures (“novel mental step”) is a matter of opinion.

Pallin offered an enlightening rebuke of CEJA’s distinction between products and methods by distinguishing incentive and reimbursement:

“it seems to me that the patent system exists for providing incentive. It does not exist solely for reimbursement. You hear that a lot. Reimbursement is important to large corporations that spend millions of dollars on research and development. They wouldn’t spend that money or invest in a device or a method if they couldn’t get a return on their investment. But the patent system was not built for reimbursement. It was built for incentives. In the Federalist Papers, you get the sense reading them that the Founding Fathers regarded

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<sup>53</sup> “Patenting of Medical Procedures,” pp. 7-8.





intellectual property as very similar to other forms of private property.

The theft or conversion of intellectual property they felt was every bit as egregious as a theft of real property or personal items. We exist today under the same patent system that they erected. I see no reason to abolish that in the single case of physicians.”<sup>54</sup>

But perhaps more convincing than the philosophical discussion of the role of the patent system was Pallin’s challenge to the premise that methods cost much less than products:

“I do not think it is safe to assume that every new incision or new swipe with a pap smear brush is one, going to cost nothing, or two, going to be obvious. If it’s...obvious, it won’t get a patent and there won’t be any cost to society.”<sup>55</sup>

Singer held a different view:

“Where there are no capital expenditures needed to develop and market or manufacture a new medical procedure, there should not be any cost to society for granting a 20-year exclusive ownership of that procedure.”<sup>56</sup>

CEJA hits upon what is perhaps an inescapable trend of commercialization in the biomedical sciences. CEJA seems to believe that patenting to earn financial reward is not a convincing reason to grant medical process patents. Yet it does not mention that this occurs with product patents. It states that recovery costs for devices or pharmaceuticals are greater than for procedures. Yet recovery costs can

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<sup>54</sup> Hearing, p. 47.

<sup>55</sup> Hearing, p. 50.

<sup>56</sup> Hearing, p. 50.



constitute financial reward. CEJA is inconsistent. Also, in its world, there would be some procedures deserving of patent protection (e.g., SET) that would be denied such protection.

CEJA appears to misunderstand, or fails to acknowledge, the reality of the patent system. First, the line between products and procedures can be blurred. Second, given the option of patenting either the product or method component of an invention, inventors will patent the product because a product patent is easier to enforce and therefore generates higher royalty revenue.<sup>57</sup> Thus, procedure patents can be disguised as product patents (or method-of-use patents). The AMA's distinction becomes weak, if not spurious.

Having made its argument against procedure patents, CEJA turned to how its view of the world could be met. It found troubling the alleged notion that the U.S. Patent and Trademark Office (PTO) was granting biotechnology patents liberally and then relying on court cases to eliminate non-obvious and non-novel patents.<sup>58</sup> CEJA believes this will raise costs. Because of this alleged approach at the PTO, CEJA believes regulating medical procedure patents is "not tenable." CEJA alluded to *Pallin v. Singer* in commenting on regulation: "Unfortunately, as supported by the recent furor [over] the patenting of medical procedures, there is a significant gap between a strict interpretation of novel and non-obvious and the way that these terms are currently applied in assessing patent applications." Thus, in CEJA's view, because the regulatory apparatus (the PTO) can, in theory but not in practice, distinguish between appropriate and inappropriate medical process patents (defined by novelty and nonobviousness, not ethical criteria), regulation is not a good option. Therefore, it advocates prohibition.

However, G. Lee Skillington, Counsel for Legislative and International Affairs at the PTO, believed the advocates of banning medical method patents combined the issue of practical implementation with ethical concerns.<sup>59</sup> Skillington noted that CEJA's distinction between appropriate and inappropriate patents was based on legality not ethics. However, the CEJA report seemed to imply a basis in ethics. Appropriate patents are those that have been conferred on inventions worthy of patent protection – that is, those that meet patent criteria. Skillington agreed with CEJA on this point but disagreed with its

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<sup>57</sup> Interview with U.S. Patent and Trademark Office Examiner, April 1998, p. 1. Hereafter "PTO examiner interview." The examiner prefers not to be identified.

<sup>58</sup> "Patenting of Medical Procedures," p. 8.



prescription for remedy. He believed the AMA's perceived problem could be solved administratively without enacting legislative prohibition.

What CEJA failed to note is that distinguishing between "appropriate" and "inappropriate" (or patentable and non-patentable) patents happens across all fields of innovative activity. Court precedent gets established over time, and not every actor in a given industry is content with PTO decisions. If CEJA's thinking were applied across all industries, but especially in relatively new and rapidly developing industries, such as biotechnology and computer software, the PTO would cease to grant method patents altogether. CEJA did not acknowledge what effects its line of thinking, if legally implemented, would have on other industries and the patent system as a whole.

CEJA was trying hard to prove its position. Even, at the outset of its report, it reluctantly conceded that the patent statutes and the 1980 Supreme Court ruling in *Diamond v. Chakrabarty*<sup>60</sup> make medical process patents valid. Also, CEJA made its political intentions implicitly clear. Referring to the 1980 Supreme Court decision, CEJA stated, "This decision to broadly interpret the statutory scope of patentable inventions makes it highly unlikely that medical procedures can be legally excluded from the legal definition of process without additional legislative action."<sup>61</sup> Finally, CEJA avoided addressing perhaps the most significant problem with its distinction between product and method patents:

"Medical process patents which involve the patenting of a procedure in conjunction with a device or drug fall outside the scope of this report, as do patents for devices without which a procedure cannot be performed [i.e., method-of-use patents]."<sup>62</sup>

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<sup>59</sup> Hearing, p. 30.

<sup>60</sup> The Supreme Court ruled that genetically-engineered organisms and "anything under the sun that is made by man" constitutes patentable subject matter.

<sup>61</sup> "Patenting of Medical Procedures," p. 2.

<sup>62</sup> "Patenting of Medical Procedures," p. 2.



The only legitimate distinction between product and procedure patents is that in the latter, the threat of an infringement suit against a physician is greater. CEJA did not offer much in the way of solutions to the problems it raised, except prohibition of patenting medical processes.

### Developing the AMA position on medical patenting

It is interesting to track over time the AMA's position on the patenting of medical products and procedures because the AMA has held a prominent position within the medical profession and because it demonstrated professional leadership in addressing the issues raised by *Pallin v. Singer*. Early on, the AMA opposed patenting of medical inventions by physicians. But over time, as medical practice and medical innovation changed, the AMA allowed and even encouraged patenting. During one period, it even assumed the responsibility of managing medical patents on behalf of physicians and the public. Past debates are relevant to debates today. The credibility and development of the AMA's current position can be assessed in the context of historical precedent. Provided here is a cursory review of the AMA's historical positions on medical patents.

While the AMA has historically opposed patenting, there has always existed pressure from within to weaken and reverse this position. At the 1846 and 1847 AMA national conventions, when the American medical profession was concerned about false claims of medicinal efficacy and the lack of dignity in physician advertising, the AMA deemed it "derogatory to professional character" for a physician to hold a patent on a medicine or surgical instrument.<sup>63</sup> In 1854, the Ohio delegation to the House of Delegates proposed deleting the ethical prohibition on holding a patent on a surgical instrument, specified in the Code of Medical Ethics.<sup>64</sup> A year later, the House of Delegates passed a resolution notifying the Ohio delegation that it would not be represented in the AMA if it did not rescind its proposed amendment. Nevertheless, the same proposal reemerged in 1894-95 and 1909.<sup>65</sup> In 1909, the House of Delegates referred the proposal to the Judicial Council for review. In 1932, in response to a proposal that the AMA's Principles

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<sup>63</sup> "Proceedings of the National Medical Conventions Held in New York, May 1846, and in Philadelphia, May 1847," p. 98.

<sup>64</sup> Blasingame, F. "1846-1958 / Digest of Official Actions / American Medical Association," p. 547.

<sup>65</sup> Blasingame, F. "1846-1958 / Digest of Official Actions / American Medical Association," p. 548.





of Medical Ethics be revised to allow physicians to secure patents, the House of Delegates and Judicial Council deemed the present Principles of Medical Ethics to be adequate on the subject of patents.<sup>66</sup>

Elements of the debate inspired by *Pallin v. Singer*, such as the tension between professionalism and private ownership, were evident in the 1800's. Dr. J. Marion Sims, AMA President in 1876, foreshadowed the arguments of today's patenting proponents:

"It is derogatory to professional character for a physician to take out a patent for a surgical instrument or any other invention. A distinguished physician invents a galvanic cautery. He has spent much time and a large amount of money in perfecting his apparatus. According to our Code, he cannot, he dare not, take out a patent for it as any other honest man could do, simply because he is a practising physician. But why should not the physician reap the reward due to talent and inventive genius as well as any other man? Does the profession at large, or does the public, derive any benefit by thus depriving him of his invention? None whatever. We simply compel him to give his invention, his time and labor, to enrich the instrument maker. A few brave men, daring to assert their inalienable rights, would soon establish a precedent that would ultimately become a law, rendering this clause of the Code, as in other instances, a dead letter."<sup>67</sup>

Sims seems to have focused his comments on product patents and the relationship between physician and industrialist. Sims would probably have considered Pallin to be one of a "few brave men." But how he would have viewed one physician suing another over a method is a speculative matter.

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<sup>66</sup> Blasingame, F. "1846-1958 / Digest of Official Actions / American Medical Association," p. 549.

<sup>67</sup> From the 1876 presidential address of Dr. J. Marion Sims. In his history of the AMA Judicial Council, Bernard Hirsh, a legal consultant to the Judicial Council in the 1960s, 70s, and early 80s, excerpts key paragraphs from a speech given by Dr. Sims. Hirsh believes Sims was "a century ahead of his time in his



In 1933, the AMA Board of Trustees and the Judicial Council conducted a joint session to discuss whether or not to continue to uphold one of the AMA's Principles of Medical Ethics which deems it "unprofessional to receive remuneration from patents for surgical instruments or medicines."<sup>68</sup> The editor of *The Journal of the American Medical Association* prepared an editorial, entitled "Problem of Medical Patents," for the Board.<sup>69</sup> The editorial began by recognizing that the topic of medical patents had been "hotly debated" and then raised key issues, many of which were relevant to the public debate in 1995.

In the editor's view, the fact that physicians were no longer creating innovations disposed medical research to patenting. Physicians were relying on manufacturers to use laboratory discoveries to produce and distribute remedies. Also, non-physician specialists, such as physicists, laboratory technicians, and biochemists, "who may not themselves be concerned at all with the traditions of medicine as a profession" were entering into medical research.<sup>70</sup> Another factor that disposed medical research to patenting was the reality that an unpatented discovery could be misappropriated by another who would steal not only the discovery but also potential profits.

The editorial looked favorably on the trend of patenting through universities, which allowed physicians to avoid recriminations for patenting, created a new stream of research funding, and facilitated the flow of rewards to the investigator via research funding. However, this practice apparently led to a "royalty crazy" environment in which researchers were jealous of one another and tended to skew their work towards developing new products without critical review.<sup>71</sup> The editorial raised the possibility that an amateur researcher who held a medical patent might try to determine the value of a compound when this was more properly the province of physicians conducting clinical trials.<sup>72</sup>

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philosophy concerning medical ethics." Hirsh, Bernard, "The History of the Judicial Council of the American Medical Association," 1984, pp. 70-2.

<sup>68</sup> Hirsh, Bernard. "The History of the Judicial Council of the American Medical Association," 1984, p. 87.

<sup>69</sup> "Problem of Medical Patents," 1933. Reprinted in Fishbein, Morris. A History of The American Medical Association 1847 to 1947, Philadelphia: W. B. Saunders Company, 1947, pp. 400-402.

<sup>70</sup> "Problem of Medical Patents," p. 400.

<sup>71</sup> Editorial cites an article by Dr. Allen Gregg (*Science*: 77 (257), March 10, 1933).

<sup>72</sup> Editorial cites Sir Henry Dale, then the director of the National Institute for Medical Research in London. While Dale viewed medical patents as dangerous, he saw chemical patents to be relatively benign because only vast industrial organizations could prepare compounds at low prices. Dale touches upon the tension between quality of the product (ethics of patient care) and access to the product by way of cost (economics). Dale, H. "Academic and Industrial Research in the Field of Therapeutics," address at the opening ceremony of the Research Laboratory of Merck & Company, Rahway, NJ, April 25, 1933.



Finally, the editorial concluded that changes in medical practice and research, as well as the rise of industrial development, seemed to require a change in the medical profession's view of medical patents. The editor advocated the creation of a central body, perhaps endorsed by the AMA, that would control medical patents in the interests of advancing medical science and benefiting the public. In the editor's words:

“Conceivably the best interests would be served in some central body that might be developed, wholly altruistic in character, capable of administering medical patents for the benefit of the public, and assuring a reasonable remuneration to the investigator, the devotion of much of the profit to research, and adequate returns to manufacturers willing to develop quantity production and distribution in an ethical manner. Such a central body might also set up requirements for adequate clinical research in connection with the development of new products, so that premature launching of unestablished products on the medical profession or on the public might be avoided.”<sup>73</sup>

Of course, agreeing on “reasonable remuneration,” “adequate returns,” and “requirements for adequate clinical research”<sup>74</sup> probably proved difficult.

The proposal for a central body to manage patents was pursued seriously in the 1930s, but the notion of managing patents was pursued in 1914. In 1914, the House of Delegates adopted a resolution which permitted the AMA to accept and manage patents on “anything whatsoever that may be used in the treatment of disease or infirmity and for which a patent may be issued” including chemical substances and

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<sup>73</sup> “Problem of Medical Patents,” pp. 401-2.

<sup>74</sup> This function has been assumed by the Food and Drug Administration (FDA).



surgical tools.<sup>75</sup> The patent donor was required to forgo royalties. The AMA would not exact patent royalties from a manufacturer unless it was in the public or professional benefit.

The AMA later managed the patent on thyroxin. Although the patent was eventually returned to the original patentholder, the Mayo Clinic, the Judicial Council declared in 1918 that it was not ethical for the Mayo brothers to use commercial profits from the patent to enlarge a fund given to them by the University of Minnesota, and it was not ethical for the University of Minnesota to accept patents on medical discoveries.<sup>76</sup> In the Judicial Council's view, the use to which profits from patent enforcement were applied did not diminish or overcome the unethical status of patenting medical discoveries. However, the House of Delegates disagreed with the Judicial Council and decided that what the University of Minnesota did with the thyroxin patent was its prerogative because the Mayo brothers had altruistically offered the patent.

In 1934, the House of Delegates requested that the Board of Trustees appoint a committee to examine a system of control on patents and devices.<sup>77</sup> In 1938, the House of Delegates supported a Board of Trustees plan to standardize and coordinate medical patents. However, in 1952, the House of Delegates and the Board of Trustees concurred that the AMA or any corporate entity controlled or financed by it should not engage in a program of patent management.<sup>78</sup>

In 1939 and 1940, the House of Delegates expanded the list of items for which physicians could not take remuneration to include "surgical instruments, appliances, medicines, foods, methods or procedures."<sup>79</sup> In the 1953 to 1955 timeframe, the House of Delegates amended the Principles of Medical Ethics to allow physicians to secure patents. The amended Principles read:

"A physician may patent surgical instruments, appliances, and  
medicines or copyright publications, methods, and procedures. The

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<sup>75</sup> The resolution was passed in 1914 and expanded in 1916. Blasingame, F. "1846-1958 / Digest of Official Actions / American Medical Association," p. 549.

<sup>76</sup> Hirsh, Bernard. "The History of the Judicial Council of the American Medical Association," 1984, pp. 83-4.

<sup>77</sup> Blasingame, p. 549-50.

<sup>78</sup> Blasingame, p. 550.

<sup>79</sup> Blasingame, p. 550.





use of such patents or copyrights or the receipt of remuneration from them which retards or inhibits research or restricts the benefits derivable therefrom is unethical.”<sup>80</sup>

By 1971, the permissibility of patenting had gained a stronger foundation. The AMA acknowledged the validity of the patent system, declared that one is entitled to protect his discovery, and deemed aggrandizement and furthering financial interest as unethical:

“It is not unethical for a physician to patent a surgical or diagnostic instrument he has discovered or developed. Our laws governing patents are based on the sound doctrine that one is entitled to protect his discovery. Medicine, recognizing the validity of our patent law system, accepts it, but in the interest of the public welfare and the dignity of the profession insists that once a patent is obtained by a physician for his own protection, the physician may not ethically use his patent right to retard or inhibit research or to restrict the benefit derivable from the patented article. Any physician who obtains a patent and uses it for his own aggrandizement or financial interest to the detriment of the profession or the public is acting unethically.”<sup>81</sup>

By the late 1970s, the AMA policy regarding patenting had shed clauses against using a patent for financial interests.<sup>82</sup>

In 1996, the AMA opined that it was unethical to patent medical procedures:

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<sup>80</sup> Blasingame, p. 550. From *Principles of Medical Ethics*, 1955 edition, Chapter I, Section 7.

<sup>81</sup> “Opinions and Reports of the Judicial Council,” 1971, p. 13.

<sup>82</sup> “Opinions and Reports of the Judicial Council,” 1977/1979, p. 53.



“A physician has the ethical responsibility not only to learn from but also to contribute to the total store of scientific knowledge when possible. Physicians should strive to advance medical science and make their advances known to patients, colleagues, and the public. This obligation provides not merely incentive but imperative to innovate and share ensuing advances. The patenting of medical procedures poses substantial risks to the effective practice of medicine by limiting the availability of new procedures to patients and should be condemned on this basis. Accordingly, it is unethical for physicians to seek, secure, or enforce patents on medical procedures.”<sup>83</sup>

The AMA’s views of patenting have changed over time, and debate over patenting medical procedures in the 1990s has echoed issues raised in the past.

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<sup>83</sup> Opinion 9.095 “Patenting of Medical Procedures,” Code of Medical Ethics / Current Opinions, 1998-1999, pp. 88-9.



## XI. Congressional involvement

As *Pallin v. Singer* forged ahead, the AMA and other medical organizations condemned the practice of patenting medical procedures and simultaneously initiated a campaign to legislate against the patenting of medical procedures. They banded together to form the Medical Procedure Patents Coalition.<sup>1</sup> Under the leadership of the American Society of Cataract and Refractive Surgery (ASCRS), the Coalition first rallied support behind the “Medical Procedures Innovation and Affordability Act” (H.R. 1127), a House bill that prohibited the issuance of patents on pure medical methods. It was introduced on March 3, 1995 by Representatives Greg Ganske (R-IA), a plastic and reconstructive surgeon, and Ron Wyden (D-OR), three months before the AMA Council on Ethical and Judicial Affairs released its report on patenting medical procedures and just two months before Judge Billings denied the defense’s request for summary judgment in *Pallin v. Singer*.<sup>2</sup> H.R. 1127 essentially read as follows:

“On or after the date of the enactment of this Act, a patent may not be issued for any invention or discovery of a technique, method, or process for performing a surgical or medical procedure, administering a surgical or medical therapy, or making a medical diagnosis, except that if the technique, method, or process is performed by or as a necessary component of a machine, manufacture, or composition of matter or improvement thereof which is itself patentable subject matter,

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<sup>1</sup> The members of the Medical Procedure Patents Coalition include the American Academy of Dermatology, American Academy of Ophthalmology, American Academy of Orthopaedic Surgeons, American Academy of Otolaryngology, American Association of Neurological Surgeons, American College of Radiology, American College of Surgeons, American Institute of Ultrasound in Medicine, American Medical Association, American Society of Anesthesiologists, American Society of Cataract and Refractive Surgery, American Society of Plastic and Reconstructive Surgeons, American Urological Association, Association of American Medical Colleges, Society of Cardiovascular and Interventional Radiology, and Society of Vascular Technology.

<sup>2</sup> “Hearing before the Subcommittee on Courts and Intellectual Property of the Committee on the Judiciary / House of Representatives / One Hundred Fourth Congress, First Session on H.R. 1127: Medical Procedures Innovation and Affordability Act and H.R. 2419: Inventor Protection Act of 1995,” October 19, 1995. U.S. Government Printing Office: Washington, p. 23.



the patent on such machine, manufacture, or composition of matter may claim such technique, method, or process.”

There were effectively three sides in the debate over this bill. The main players were the American Medical Association (AMA), American Society of Cataract and Refractive Surgery (ASCRS), and the Medical Procedure Patents Coalition on one side and the American Bar Association (ABA), American Intellectual Property Law Association (AIPLA), and the Department of Commerce (DoC) on the other side. But the Biotechnology Industry Organization and the Pharmaceutical Research and Manufacturers of America took a third position. They, like the ABA, AIPLA, and DoC, opposed H.R. 1127. But their opposition derived primarily from a fear of the bill’s ill effects on the biotechnology and pharmaceutical industry and not from a desire to preserve the integrity of the patent system or to strengthen the trade negotiating position of the United States. Thus, much more than medical ethics was at stake.

A milder form of H.R. 1127’s prescription for change emerged in the fall of 1995. On October 18, 1995, Senator Bill Frist (R-TN), a heart and lung transplant surgeon, introduced S. 1334, also entitled “Medical Procedures Innovation and Affordability Act,” which banned the enforcement of medical method patents against health care providers. This bill aimed to change infringement liability, not what is considered patentable subject matter. It read:

“For any patent issued on or after the effective date of this subsection, it shall not be an act of infringement for a patient, physician, or other licensed healthcare practitioner, or healthcare entity with which a physician or licensed healthcare practitioner is professionally affiliated, to use or induce others to use a patented technique, method, or process for performing a surgical or medical procedure, administering a surgical or medical therapy, or making a medical diagnosis. This section does not apply to the use of, or inducement to use, such a patented technique, method, or process by any person engaged in the





commercial manufacture, sale, or offer for sale of a drug, medical device, process, or other product that is subject to regulation under the Federal Food Drug, and Cosmetic Act or the Public Health Service Act.”<sup>3</sup>

Health care providers would be immune to medical method patent infringement lawsuits. S. 1334 proved to be more palatable than H.R. 1127, but it was H.R. 1127 that initiated Congressional involvement in the patenting of medical methods. Although Pallin had few defenders among physicians, the Congressional debate showed that Pallin’s greatest allies were patent attorneys.

### Soliciting Views in a Hearing

#### *The Legislators*

On October 19, 1995, approximately a half year after Representatives Ganske and Wyden introduced H.R. 1127 and one day after Senator Frist introduced S. 1334, the House Subcommittee on Courts and Intellectual Property (under the House Judiciary Committee) held a hearing to discuss H.R. 1127.<sup>4</sup> Both the Subcommittee’s chairman and ranking member, Representatives Carlos Moorehead (R-CA) and Patricia Schroeder (D-CO) respectively, placed the burden of proof for the necessity of H.R. 1127 on the shoulders of the bill’s proponents. Schroeder declared that she assumed the validity of the Founding Fathers’ view that conferring exclusive rights would promote the progress of science, but added that she was open to hearing about aspects of the patent system that do not meet this goal.<sup>5</sup>

Representatives Ganske and Wyden believed that medical method patents hindered medical progress and the affordability of medical care. Ganske testified that medical advances are made by the incremental and collaborative steps of many physicians. He pointed out that two of his mentors, Dr. Starzl who performed the first successful liver transplant and Dr. Murray who performed the first successful

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<sup>3</sup> S. 1334, 104<sup>th</sup> Congress, 1<sup>st</sup> Session.

<sup>4</sup> “Hearing before the Subcommittee on Courts and Intellectual Property of the Committee on the Judiciary / House of Representatives / One Hundred Fourth Congress, First Session on H.R. 1127: Medical Procedures Innovation and Affordability Act and H.R. 2419: Inventor Protection Act of 1995,” October 19, 1995. U.S. Government Printing Office: Washington. Hereafter referred to as “Hearing.”



kidney transplant, did not patent their work. Ganske believed the Patent and Trademark Office (PTO) lacked the requisite knowledge of medical science to determine patentability, and therefore, it granted intellectual property rights when they were not deserved. Ganske distilled his primary issue to an analogy with a dessert:

“Mr. Chairman, the practice of patenting medical procedures is flat wrong. Some doctors have made minor changes in a technique and are claiming intellectual property over an entire procedure. They have put the cherry on top of the whipped cream, and are seeking to patent the entire banana split.”<sup>6</sup>

While Wyden also saw the central issue to be the impropriety of granting to an individual exclusive rights to inventions developed by others, Wyden was concerned more with health care costs.

“limiting medical procedure patents is critical because otherwise what you are going to have in this country is a handful of physicians profiting enormously from these procedures, while the majority of consumers and the majority of physicians in our country pay through the nose.”<sup>7</sup>

Noting that Congress was concurrently debating solutions to the problem of escalating Medicare costs, Wyden viewed medical procedure patents as another agent of upward pressure on health care costs.

*The Principals in Pallin v. Singer*

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<sup>5</sup> Hearing, p. 23.

<sup>6</sup> Hearing, p. 25.

<sup>7</sup> Hearing, pp. 25-6.



As Pallin and Singer awaited the start of their trial, they continued sparring, but now in a more public forum. Leaving aside legal technicalities and the specifics of *Pallin v. Singer*, both men presented their visions for the outcome of the legislative debate.

Although H.R. 1127 would not apply to his patent, Pallin said he testified because he was concerned about the future of medical innovation.<sup>8</sup> Pallin's prepared testimony opened with an appeal to the human side of his audience:

"I am a physician and the medical director of the Lear Eye Clinic in Scottsdale, Arizona. I am also an American, a son and a father. My father is a retired physician and my son is a physician. From time to time I have also been fortunate to be a patient under our wonderful medical system. And I am also an inventor."<sup>9</sup>

Pallin believes the controversy over patenting medical methods, although sparked by his lawsuit against Singer, had occurred primarily for two reasons. First, physicians had discovered patents as an alternative to publications. Pallin saw the U.S. Constitution, through the patent system, to be "impartial and manifestly fair" in contrast to the world of medical politics – presumably a reference to the journal editors that denied him publication. The medical establishment could not exert the same control over the flow of ideas now as it had done in the past. The second reason for the controversy lay in improved enforcement of intellectual ownership of medical inventions, which was made possible by the computerization of medical record data. Pallin testified, "patent owners would sooner or later attempt to enforce their rights under the law as the information age progressed. And here we are, at this point in time, dealing with a body of American physicians unaccustomed to honoring patent law."<sup>10</sup>

However, Singer believes the controversy over patenting medical procedures stems from a conflict between medical ethics and U.S. patent policy:

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<sup>8</sup> Hearing, p. 40.

<sup>9</sup> Hearing, p. 40.

<sup>10</sup> Hearing, p. 41.



“The free exchange of medical and surgical methods cannot coexist with the monopoly-dependent exchange of the patent system. Two entirely different sets of values and incentives will work against each other, and only one will survive. I hope the free exchange system will prevail, for it places the needs of our patients, the medical profession, and the health and welfare of our society first. The only individuals who stand to benefit from a monopoly dependent medical method exchange system are medical method patent owners and their lawyers.”<sup>11</sup>

Singer worried that physicians would not share or use information and techniques for fear that they would become the targets of patent infringement lawsuits. Hindering the free exchange of knowledge and adding licensing fees, royalties, patent searches, patent applications, legal expenses, and liability insurance would increase health care costs. While Singer conceded that patents promote disclosure, he believes the patent system will delay disclosure for months after the patent application is filed. A delay of even six months would hinder medical advances because, as he pointed out, an eye surgery method can be improved in 6-12 months with the free dissemination of knowledge. Also, in Singer’s view, if use of a patented method is circumscribed, then disclosure via patents falls short of physicians’ ethical obligations to treat patients. Finally, Singer warned that the vast pool of unpatented medical knowledge constituted a “gold mine” that could be misappropriated by people who did not develop such knowledge. The solution, in Singer’s eyes, was legislative prohibition.

Yet, Singer conceded the benefits of patents in encouraging investment in medical drug and device development:

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<sup>11</sup> Hearing, p. 46.





“Patents can serve a useful function and provide a public benefit to encourage investment in research, development, and manufacture of new devices and new drugs and to finance testing for FDA approval. There is no manufacturing and testing required for medical and surgical procedures, and their development usually emanates from intellectual curiosity, creativity, and compassion for patients rather than the availability of capital. There is no public benefit to patenting medical procedures where there are no high costs for development or testing, and no manufacturing is required.”<sup>12</sup>

Singer agreed that patents promote invention and yet said there was no benefit from patenting cheaply developed procedures. On the contrary, the public would appear to benefit by the very existence of the procedure.<sup>13</sup>

Pallin argued that medical method patents should be allowed because statutes and court precedent have deemed them permissible, incentives and motivation are important for medical progress, and the law should apply to all citizens equally. Pallin noted that even the report of the AMA Council on Ethical and Judicial Affairs (CEJA) on patenting medical procedures had conceded that it was “highly unlikely” that procedure patents could be prohibited in light of existing law and precedent. In Pallin’s view, physicians possess no incentives to control costs in a managed care environment because they are salaried employees. Thus, the incentive of compensation from patents would motivate physicians to continue inventing. However, Representative Hoke (R-OH), a member of the Subcommittee, found this idea to be “misguided” in light of the fact that fixed-salary physicians at institutions such as the Cleveland Clinic have devised innovative heart surgery procedures without additional incentives.<sup>14</sup> Nevertheless, Pallin asked why reward

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<sup>12</sup> Of note, in this paragraph, he does not confine his words to *pure* methods but discusses procedures generally. Hearing, p. 44.

<sup>13</sup> It might be asked of Singer, as well as the AMA CEJA, how the acceptability of procedure patents changes if the procedure possesses high development or testing costs, and requires manufacturing.

<sup>14</sup> Hearing, pp. 50-51.



should be withheld from an inventor, particularly if the patented invention reduces costs. Pallin's most compelling argument may have been embodied in the following paragraph:

"Now if the engineers of America came to you and said, 'We want you to pass legislation exempting discoveries in our field from patent law. We want to be the only group in America that is not required to recognize new discoveries by taking licenses or paying royalties.' What would you say to them? One day an engineer may make a discovery which benefits all humanity. Would you tell that engineer that no recognition will be given by the Patent Office to his idea? Why not exempt pharmacists, chemists, genetic engineers, or computer scientists? No, Gentlemen and Ladies; if we are to have a patent system, and the Constitution says we shall have, then it must apply to all of us equally."<sup>15</sup>

Pallin pointed to a Pandora's box of legal implications.

Pallin then criticized organized medicine and its arguments against patenting medical methods. Pallin questioned the claimed altruism of organized medicine and portrayed organized medicine as a special interest group in search of privilege. Pallin noted that the medical lobby only concerned itself with medical procedure patents when he had brought suit against Singer, even though such patents were granted before the start of *Pallin v. Singer*. Characterizing the AMA's distinction between patents on methods and devices as "dubious," Pallin wrote, "The medical lobby has apparently reversed its position and now wishes to facilitate physician patents on devices but make methods unpatentable. This is inconsistent."<sup>16</sup> Pallin testified that he had been advised to link his method to an instrument which he could patent and earn royalties from, but he does not condone this practice:

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<sup>15</sup> Hearing, p. 41.



“In fact, I was told that the proper way to proceed was for me to devise some kind of instrument to go with my operation since that was more traditional; therefore more ethical. I could have an instrument manufacturer rebate royalties to me for use of my intellectual property. Ladies and Gentlemen, that is a deception. If you pass H.R. 1127 you will participate in that deception and force doctors to do the same. I ask you to resist the influence of the medical lobby and do what is right.”<sup>17</sup>

Representatives Moorehead and Schroeder, the chairman and ranking member of the committee, remained skeptical as they challenged the views of Pallin and Singer. Representative Moorehead asked Pallin what he thought of the alleged scenario that physicians would have to navigate a web of royalties and licenses in order to use simple medical procedures. Pallin downplayed the magnitude of any potential problem:

“Commercial patents on drugs and instruments will always dominate medicine and surgery. Doctors deal with dozens of those every day, whether they recognize this or not. Method patents will be a minor concern by comparison.”<sup>18</sup>

Pallin tried to allay fears of increasing health care costs by explaining that patents such as his create cost savings. He explained that his sutureless incision saves \$17 per operation. Spread over a million cataract operations per year in the U.S., the \$17 million saved would still provide a saving even if a royalty of \$3-5 were charged. Pallin urged Congress not to sacrifice the incentives of the patent system.

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<sup>16</sup> Hearing, p. 42.

<sup>17</sup> Hearing, p. 42.

<sup>18</sup> Hearing, p. 47.



Representative Schroeder offered one of the toughest challenges to distinguishing products and procedures when she asked Singer what he thought of a scenario in which a medical device possessed low R&D costs, such as a pap smear brush.<sup>19</sup> Singer did not squarely address the question. He simply reiterated his position.<sup>20</sup> Schroeder complicated the scenario by bringing up the idea of a cheap device for which an inventor develops a new use.<sup>21</sup> Singer declared that exceptions to the rationale behind his distinction between products and processes may arise, but this did not overcome the detriment of the loss of the free exchange of information.<sup>22</sup>

### *The Professional Interests*

Having heard from the principals in *Pallin v. Singer*, the Subcommittee turned to officers of organized medicine and organized law, a U.S. Patent and Trademark Office (PTO) attorney, a biotechnology CEO, and an ophthalmologist/patent attorney, all of whom disagreed on the merits of prohibiting medical method patents but appeared to agree on the need for an option more palatable than H.R. 1127. Dr. Charles Kelman, inventor of phacoemulsification and the president of the ASCRS, and Dr. Dunbar Hoskins, executive vice-president of the American Academy of Ophthalmology, represented the interests of the AMA and other members of the Medical Procedure Patents Coalition.<sup>23</sup> Kelman supported the intentions of H.R. 1127 because he believed the “enforcement of medical method patents against physicians [would] inevitably corrupt and commercialize the art and science of medicine, while limiting the widespread availability of new advances.”<sup>24</sup> All other witnesses opposed H.R. 1127. G. Lee

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<sup>19</sup> Moorehead noted that some procedures require extensive R&D funding and would not have been developed without patent protection.

<sup>20</sup> “I think there is a clear distinction between medical procedures and devices, Representative Schroeder. All devices require some sort of capital expenditure for development and marketing and manufacturing. Whereas a pure procedure like the shape of an incision does not require any capital or research and development, marketing, or manufacturing.” Hearing, p. 49.

<sup>21</sup> But there was no time for a response from the principals.

<sup>22</sup> Hearing, p. 47.

<sup>23</sup> Kelman attempted to build strong credibility by declaring that he held over 100 patents and had invented numerous products and methods. Kelman noted that his phacoemulsification machine saves the government an estimated \$7 billion per year in hospitalization costs. One could argue that Pallin analogously describes the virtues of his patent in saving money. Kelman remarks that he did not patent pure medical methods, except where it was necessary as part of a defensive patent management strategy. Hearing, p. 54.

<sup>24</sup> Hearing, p. 59.





Skillington, Counsel for Legislative and International Affairs at the PTO since 1981, whose job it is to advise the PTO on bills affecting intellectual property law, saw H.R. 1127 as an “overkill” solution:

“To deny patentability to these kinds of inventions to solve the problems presented is like trying to cut your fingernails using a chain saw. It does not come out with the required result.”<sup>25</sup>

Donald Dunner, Chair of the Section of Intellectual Property Law of the American Bar Association, believed that while the proponents of H.R. 1127 had good intentions, they had a “fundamental misunderstanding” of how the intellectual property system works.<sup>26</sup> Michael Kirk, Executive Director of the American Intellectual Property Law Association and former PTO Deputy Commissioner with over 30 years of experience at the PTO, believed H.R. 1127 proponents had not built a convincing case. Dr. Frank Baldino, President and CEO of Cephalon, Inc., testifying on behalf of the Biotechnology Industry Organization (BIO), agreed with what he saw as the motivation of H.R. 1127 – to decrease lawsuits – but believed the bill, if enacted, would eliminate method-of-use patents which are required for biotechnology R&D investment. Dr. William Noonan, an ophthalmologist and a patent attorney who has written on patenting in biotechnology and medicine, agreed. Although Noonan supported limitations on surgical procedure patents, he saw H.R. 1127 as “an overbroad response to the ethical problem of procedure patents in medicine”<sup>27</sup> because it would not allow protection for new uses of unpatentable medical inventions, such as drugs, devices, and biotechnology products.

In Kirk’s view, the controversy over medical patenting had arisen because nearly 40 years ago the AMA CEJA deemed it not unethical to patent medical inventions, and now one physician was suing another over infringement of a medical method patent. He wrote that *Pallin v. Singer* was not about

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<sup>25</sup> Hearing, p. 28.

<sup>26</sup> Hearing, p. 79.

<sup>27</sup> Hearing, p. 67.



prohibiting the use of a method because Pallin had shared his cost-saving development with the medical community by offering a license. The defendants were merely unwilling to purchase a license.”<sup>28</sup>

Noonan noted that controversy over patenting in medicine was not new. He observed that despite the long history of patents in medicine, procedure patents only recently entered the public debate because physicians began to enforce their patents against other physicians. Noonan believes there is little litigation in the area of medical method patents because of the traditional ethics of physicians and the impracticality of enforcement.<sup>29</sup> As to why the controversy had come before Congress, Noonan wrote that when the Supreme Court had ruled in 1980 that even living organisms are patentable, it stated it would not bar the patentability of certain subject matter in order to achieve policy objectives.<sup>30</sup> It said policy was an issue for Congress.

The issue was much larger than *Pallin v. Singer*. Noonan believed the central dilemma in the controversy over medical procedure patents was choosing between economic & technological benefits and the freedom of physicians in choosing procedures, but he urged Congress to consider the ethics of medical care:

“Like so many problems in medicine, the controversy over procedure patents is complicated by ethical overtones. Medical care is not just another consumer product the regulation of which should be left to the marketplace. Access to appropriate medical care literally determines whether some people live or die. Access to the best surgical treatment may make the difference between a lifetime of sight or blindness. Any

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<sup>28</sup> Hearing, p. 89.

<sup>29</sup> The latter stems from difficulty in monitoring and enforcing patents against infringing physicians who are widely distributed and number in the thousands. It is easier to monitor a few mass producers and enforce injunctions against them than to individually sue physicians. Noonan illustrated the monitoring problem by describing Dr. Mark Stephen’s patent on a method to determine fetus gender by ultrasound. Because the essence of the method is a thought process, the only way infringement could be practically proven is if the physician declared that he used such a method. However, Noonan did acknowledge that infringement would be easier to determine where a method is based on an automated process.

<sup>30</sup> Hearing, p. 64.



policy decision about access to such an important service must be made with this fact in mind.”<sup>31</sup>

To illustrate his point, Noonan posed the extreme scenario in which one hesitates to administer CPR (cardiopulmonary resuscitation) or the Heimlich maneuver for fear of infringing a patented method.<sup>32</sup> Less extreme, Noonan asked his audience to imagine a scenario in which an HMO restricts use of the best procedure because it costs too much to license.

Kelman was also ethically opposed to medical method patents. In Kelman’s view, given the free exchange of knowledge in medicine and the substantial variation in physician technique, “allowing someone to “own” a medical or surgical procedure is just as absurd as permitting someone to patent Ted Williams’ baseball swing or Michael Jordan’s jump shot.”<sup>33</sup> In appealing to the moral sensibilities of his audience, Kelman expressed his belief that most people would be surprised to know that a physician could patent a medical method, such as the Heimlich maneuver, and then enforce that patent.

Hoskins echoed thoughts expressed by Kelman and Singer. Explicitly referring to physicians’ knowledge and skills and not to devices and drugs, Hoskins stated that restrictions on the use of lifesaving methods seriously threatened public health.<sup>34</sup> However, with respect to *Pallin v. Singer*, Kirk pointed out that no concrete proof had been offered that patients had been placed at risk of not having the benefit of Pallin’s technique. Hoskin’s distinction between methods (knowledge and skill) and products (devices and drugs) is questionable because in order to prescribe and dose a drug (a product), physicians must use *knowledge* of drug mechanism and efficacy profiles, and *skill* in dosage calculations. Methods and products are not so discrete.

Hoskin’s main concern is that patents will restrict physician choices. He believes a physician cannot make the best clinical judgment if he has to worry about royalties and licenses. However, one could argue that the same restriction of choices exists with drugs and devices because physicians are thinking about reimbursement or cost control. Dunner asserted that medical method patents did not restrict

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<sup>31</sup> Hearing, p. 65.

<sup>32</sup> The CPR method is used to treat cardiac and respiratory arrests. The Heimlich maneuver treats choking.

<sup>33</sup> Hearing, p. 57.



physician choices because the physician would always have the option of purchasing a license. Dunner drew a parallel between method and product patents:

“Rather than directly interfering with the medical decision-making process, the cost of such a license is merely a factor in that decision-making process. Consideration of the cost of a medical method should be no different than consideration of the cost of a medical device used in the treatment of a patient.”<sup>35</sup>

He also believed the public would not be deprived of a method due to a patent:

“The proponents of this legislation also raise the specter of injunctions prohibiting physicians from using particular methods. Of course, courts will be guided by principles of equity, including the public interest and balancing of hardships, in considering a request for injunctive relief. In fact, courts routinely refuse to issue injunctions in favor of patented health care innovations where it can be shown that there is no adequate alternative available. It is therefore reasonable to conclude that the public is not likely to be deprived of any meaningful therapeutic advance as a result of patent protection.”<sup>36</sup>

Skillington said the alleged problems of reduced clinical access, interference with knowledge dissemination, and the claimed ethical imperatives of doctors to develop and share techniques were similar

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<sup>34</sup> Hearing, p. 69.

<sup>35</sup> Dunner says that “virtually the only distinction” between product and method patents is that medical providers are indemnified against patent liability with products but not with procedures. However, he says the mere fact of liability exposure does not warrant changing patent law. Dunner believes that health care costs may decrease with medical method patents that create cost savings. He believes no evidence of the opposite has been shown. Hearing, p. 82.

<sup>36</sup> Hearing, p. 82.





to issues considered in 1902 when Congress considered a bill to outlaw patents on methods of treating disease.<sup>37</sup> However, he noted that the same predictions being made now of the dire consequences of patenting medical methods were made then, but the predictions have not come true. The medical profession has flourished, in part due to the patent system. Skillington believes prohibiting the patenting of medical methods will lead to secrecy which would constitute “the worst of both worlds – a proprietary interest in a medical or surgical procedure but without its public disclosure.”<sup>38</sup> Noting that even proponents of H.R. 1127 concede that patent protection was necessary for the development of some medical methods (e.g., surrogate embryo transfer (SET)), Skillington stated that H.R. 1127 proponents had built a paradoxical position in which they sought to eliminate patents which achieve the good they desire.<sup>39</sup>

Nevertheless, both Kelman and Hoskins wrote that procedure patents would diminish the quality of medicine. Hoskins expressed concern that procedure patents would lead to breaches in patient confidentiality and to liabilities for surgeons who do not use state-of-the-art techniques. However, Dunner believes physicians will not compromise patient care.<sup>40</sup> He cited physicians’ use of TPA (tissue plasminogen activator) over the use of streptokinase for thrombolytic therapy. TPA, a drug patented by Genentech, is ten times more expensive than streptokinase, an unpatented drug, and only offers a 1% advantage in survival rate.<sup>41</sup>

Both Kelman and Hoskins believe that patent applicants will be faced with incentives to withhold information, and therefore peer review will be inadequate.<sup>42</sup> Hoskins painted a pessimistic picture in which doctors experience a conflict-of-interest when the possibility of patenting a method exists.<sup>43</sup> Kelman warned that doctors might employ untested procedures on patients in an effort to develop a patentable method. However, Kelman injured many patients’ eyes when he initially developed phacoemulsification.<sup>44</sup>

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<sup>37</sup> Hearing, p. 29.

<sup>38</sup> Hearing, p. 31.

<sup>39</sup> Hearing, p. 28.

<sup>40</sup> Hearing, p. 81.

<sup>41</sup> However, physicians may not care how expensive a drug or procedure is because a third party will pay for it. So cost is not an issue although liability might be.

<sup>42</sup> Doctors may shield their discoveries from outside scrutiny. However, Hoskins acknowledged that this can happen in academic publishing.

<sup>43</sup> Of note, Pallin identifies conflict-of-interest with medical products as similarly problematic. Pallin interview, p. 6.

<sup>44</sup> Weitzman interview, p. 13.



Perhaps paradoxically, Hoskins believes methods will not be kept secret in the absence of patents. Because methods are not mass produced but performed one at a time, it is not financially advantageous to keep new techniques secret. Kelman believes duty and recognition are sufficient to promote disclosure which is already the norm in medicine. It is an interesting statement from a man who possesses over 100 patents and enforces many of them.<sup>45</sup> But, Dunner shattered the argument that physicians will not disclose their inventions prior to obtaining a patent:

“It has been argued, in support of H.R. 1127, that medical method patents discourage doctors and researchers from sharing medical information openly with their colleagues. There is no evidence to support this assertion. Prospective patent applicants are not required to maintain secrecy until the application is filed. Indeed, the United States patent law provides a one-year grace period in which prospective applicants may disclose and publicly use their inventions before filing a patent application. If anything will cause physicians and medical researchers to rethink their long tradition of publishing their findings and innovations in professional journals, it is not the presence of patent protection which will do so, but the denial of patent protection.”<sup>46</sup>

On the subject of health care costs, Kelman seemed to demand convenience rather than propriety. He wrote, “While royalty fees on a particular procedure may be relatively small from a percentage perspective, the aggregate cost of royalties across thousands of procedures can substantially increase the

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<sup>45</sup> Kelman, like other proponents of prohibiting medical method patents, raises the behavior of famous contributors to medicine as precedent for the current controversy: “Indeed, giants of medicine like DeBakey, Starzl, Barnard, and Heimlich – people who were responsible for some of the most impressive advances in medical knowledge – never applied for patent protection because they were motivated by a desire to improve mankind and the recognition from their peers and the public that naturally flows from truly significant scientific achievements.” Whether Kelman actually knows the thoughts of these great physicians or is inferring such is not known. He may be right. On the other hand, these physicians devised their inventions at a time when the costs of peer ostracism may have outweighed financial gain. Hearing, p. 60.



nation's health care bill."<sup>47</sup> However, Kelman assumes that none of the patented procedures will save costs even though he estimates that his patented phacoemulsification technology saves the government \$7 billion per year in hospitalization costs.<sup>48</sup> Kelman further writes, "Although the inflationary effect of medical procedure patents is likely to be similar in principle to that caused by patents on devices and drugs, the cost of drug and device patents has already been built into the price of the product."<sup>49</sup> Kelman's real problem with procedure patents stems not from costs but from the inconvenience of the separation of use of a procedure and payment for using it.

Kelman believes poor review of medical procedure patent applications by the PTO leads to proliferation of patents with broad scope. Kelman said that although Pallin's technique is just a minor variation of others' incision techniques, Pallin was claiming that his patent covers what 2,000 ophthalmologists do. Kelman feared that other physicians would be able to patent minor variations of techniques and then claim the technique and all of its variations. Citing the statistic that the PTO grants 15 medical procedure patents per week, Kelman wrote: "Too often, these patents are granted based on very limited information about the true state of medical knowledge in the relevant field of medicine. Until recently such patents were rarely enforced and involved relatively obscure procedures."<sup>50</sup> But Kelman then described the high-profile cases of *Pallin v. Singer*, Dr. Mark Stephens' ultrasound patent, and the enforcement of a penile drug injection patent by Men's Health Resources, Inc. Of note, Kelman informed

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<sup>46</sup> Hearing, pp. 81-2.

<sup>47</sup> Hearing, p. 59.

<sup>48</sup> Although Kelman acknowledges that procedure patents can increase costs as product patents can, he overestimates the cost of cataract surgery procedure patents in his effort to portray method patents as major cost drivers. Kelman presents a videotape of a cataract operation during which he points out the multiple places where he or others invented a method for a step of the operative procedure. He claims that 40 method patents could be tied to the operation. He assumes \$10 royalty on each patent and one million Medicare cataract surgeries per year. Then he estimates an added cost of \$400 million to Medicare alone if these patents were obtained and enforced. Kelman says that factoring in the operative steps in other medical fields would lead to the medical system's bankruptcy. However, Kelman overestimates the cost to the health care system because he assumes all of these patents would be valid, all inventors would charge royalties at the rate he assumes, none of the patents would decrease health care costs, the patents would be mutually exclusive, and the patented steps could not be bypassed with other steps just as effective. Furthermore, we must take Kelman at his word that the operative procedures he identified would be patentable. Hearing, p. 55, 54.

<sup>49</sup> Hearing, p. 59.

<sup>50</sup> Hearing, p. 57.



the Congress that the physician who invented the surrogate embryo transfer (SET) method stated that his patent would be enforced, and licenses would be granted only to those who met his philosophy.<sup>51</sup>

Although Kelman argued that procedure patents derived by skimming off the pool of unpatented medical knowledge “arguably should not issue,” he believed that the PTO made mistakes because the patent applicant is responsible for furnishing prior art and PTO examiners are not privy to medical developments:

“These examiners have limited information about the unpublished evolution of medical science that takes place in operating rooms, physicians’ offices, conferences, and seminars, and indeed would have to be medical experts to keep up with the fast pace of medical progress.”<sup>52</sup>

Dunner argued that pirates would not misappropriate unpatentable medical knowledge in the public domain because there are severe penalties for not bringing relevant prior art to the attention of PTO examiners or for defrauding the federal government as to the identity of an inventor.<sup>53</sup>

Technically, PTO examiners need only keep up with published, or publicly disclosed, information, not “unpublished” developments (unless furnished by the patent applicant). An undisclosed finding is out of the reach of examiners, and the public for that matter. Also, examiners need not be “medical experts.” They need to be shrewd reviewers who can pose the right questions about medical technologies. Nevertheless, many examiners have built significant expertise in the field in which they examine patents.<sup>54</sup> Kelman did not acknowledge that the very issues he raised about PTO practices occur in other fields of invention, especially in rapidly developing ones like computer software and biotechnology.

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<sup>51</sup> Hearing, p. 58.

<sup>52</sup> Hearing, p. 59.

<sup>53</sup> Hearing, p. 78.

<sup>54</sup> PTO examiner interview, p. 4.





Kelman saw medical method patents as a “systemic threat to public health” that warranted a “systemic response” via legislation.<sup>55</sup> He deemed futile an administrative solution because the “Patent Office has neither the power nor the inclination to address the systemic problems raised by medical procedure patents.”<sup>56</sup> But Kelman did not support H.R. 1127 in practice because of philosophical objections of critics and the possibility of unintended precluding of acceptable patents.

Dunner believes that it is unfair and “counterproductive” to single out one area of patentable subject matter for different treatment. He stated that the patent system is premised on making patents available to any and all subject matter.<sup>57</sup> He noted that the patent system had been tested for over 200 years and had produced outstanding results.<sup>58</sup> In his view, the patent system is based on a national policy judgment that the benefits of patenting outweigh the costs. He believes this applies to medical methods also. Dunner emphasized that in the absence of incentives for invention and disclosure, duplication of effort, secrecy, and lack of investment would result as inventors would have no protection and no competitive advantage. Dunner conceded that there are costs to patenting, such as licensing fees, but believes these costs are limited by the term of the patent and the application of patent criteria by the PTO. He concurred with Representative Schroeder who said that procedure patents in medicine raise the same costs and problems as procedure patents in other fields.

Skillington expressed disappointment that the AMA did not raise the issue of medical method patents with the PTO over the last few years when the Office had held public hearings, one of which examined if the obviousness criterion was being appropriately applied in biotechnology. Thus, the PTO never had the chance to examine and address the problems. Dunner wrote that the PTO had long been granting medical method patents and has reviewed them well because their success rate is only half as high as conventional electrical and mechanical patents.<sup>59</sup> Dunner said Congress should not presume the PTO is unable to examine medical method patent applications competently.

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<sup>55</sup> Hearing, p. 60.

<sup>56</sup> Hearing, p. 60.

<sup>57</sup> Hearing, p. 79.

<sup>58</sup> Hearing, p. 80.

<sup>59</sup> Dunner is a legal expert, but it must be asked if the medical method patent application success rate is lower because of quality PTO review or lack of high-quality applications.



The impact of H.R. 1127 went beyond the PTO. Kirk asserted that enacting H.R. 1127 would undermine the stance of the U.S. in negotiations over the Trade-Related Intellectual Property aspects (TRIPs) of the General Agreement on Trade and Tariffs (GATT). The U.S. had been advocating that all technologies be eligible for patents. However, Paragraph 3, Article 27 of TRIPs allows member nations to refuse patents on diagnostic, treatment, and surgical methods for the treatment of humans, animals, and plants, except microorganisms. In Kirk's view, if the U.S. argued to exclude subject matter, other countries would establish other exclusions:

“Simply put, any form of restriction on medical or surgical patents grafted on to the U.S. patent law would be an invitation to our trading partners around the world to further compromise already anemic regimes for the protection of biotechnology inventions – as well as for inventions in other fields in response to demands by domestic pressure groups under the guise of national interest.”<sup>60</sup>

However, Hoskins believed H.R. 1127 would be consistent with GATT/TRIPs because 80 other countries and most U.S. trading partners do not allow the patenting of medical methods. While Hoskins said the concerns of U.S. manufacturers should be addressed, he noted that the U.S. did not export surgery and that physicians were not engaged in international market competition.<sup>61</sup> Noonan believed that it would be best to coordinate intellectual property law with trading partners. Because other countries already did not allow medical method patents, Noonan suggested the U.S. might gain a bargaining chip if it did not pass H.R. 1127.

Skillington advised Congress to study the reasons for medical method patent prohibitions in other countries before establishing the same in the U.S. He believes the U.S. should not change patent law so easily. He said the European Patent Convention had a mixed policy which effectively excluded surgical

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<sup>60</sup> Hearing, p. 90.

<sup>61</sup> Hearing, p. 71.



and medical procedures but noted that this policy was not universally followed. According to Skillington, some legal experts in Europe advocated eliminating the prohibition on medical method patents.

The biotechnology industry was more concerned with the prospect that H.R. 1127 would prohibit “new use” patents which, it believed, were vital to its health and the quality of medical care. New use patents cover inventions where a new use is found for an unpatentable product. For example, physicians treat AIDS with AZT and baldness with minoxidil, but physicians originally used these drugs for other diseases, and the patents on these drugs expired. Dr. Frank Baldino of Cephalon, Inc. used one of his company’s drugs in development to illustrate the problems with H.R. 1127. Cephalon would soon submit an FDA application for Myotrophin, a drug for which Cephalon had discovered a new use. The drug would be used to treat amyotrophic lateral sclerosis (ALS), or Lou Gehrig’s disease. Cephalon had secured a method-of-use patent on Myotrophin. Under H.R. 1127, the use of Myotrophin for ALS would not be patentable because Myotrophin itself was unpatentable. Baldino noted that the language of the bill prevents new use patents even though its proponents claimed the bill only affects pure medical method patents.<sup>62</sup>

Given the limitations of H.R. 1127, some of the proponents of the intentions of H.R. 1127 favored the approach of Senator Frist, who had recently introduced a bill (S. 1334) that would prohibit medical method patent infringement suits against health care providers.<sup>63</sup> Kelman saw merits in Frist’s bill. He said it would allow the issuance of patents on medical methods while protecting the medical profession from infringement suits. Furthermore, Frist’s bill would protect the enforcement capabilities of industrial

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<sup>62</sup> Baldino believes alternatives to H.R. 1127 have been hastily drafted. While he says he could not imagine a situation where a biotechnology company would sue a physician for infringement, if a rival firm sells Myotrophin to a physician and the physician prescribes it for ALS, Cephalon would send a letter to the physician. If the physician does not cease the infringing practice, costly litigation could result.

<sup>63</sup> Kelman believes the basis for Frist’s approach derives from section 271 (e) of the patent statutes which classifies as a noninfringing action the use of a patented drug or veterinary biological product as part of providing information to regulatory agencies. But Kelman’s view appears incorrect. Kelman wrote: “The policy rationale for this exception – to encourage the development of new drugs and biological products free from the threat of patent infringement – is analogous to the need to limit the enforcement of medical procedure patents to ensure the availability and quality of new medical services.” Actually, the exception is analogous to the experimental use doctrine. An individual or corporate inventor can use a patented drug or biological product without obtaining a license only if such use is for regulatory purposes (e.g., comparing efficacy of experimental drug X and already patented drug Y). Hearing, p. 61.



medical method patents. But noted Kelman, “Of course, the AMA’s ethical standards would still preclude *physicians* from seeking medical procedure patents.”<sup>64</sup>

Noonan, on the other hand, recommended no legislation because the difficulty in enforcing medical method patents had “effectively nullified” them anyway.<sup>65</sup> He believed H.R. 1127 would make U.S. law more restrictive than European law because it would prohibit new use patents and biotechnology product patents, which would have devastating economic implications. Noonan said the approach of infringement immunity for health care providers contained in Frist’s bill was specific but granted special status to one professional group, and therefore would give cause for other groups to seek similar immunity. Noonan proposed an alternative legislative solution in which patents would only be conferred on procedures which undergo FDA review.

Noonan’s most enlightening contribution lay in his view that the threat of medical method patents was insignificant.<sup>66</sup> He believes medical method patents are difficult to enforce and “therefore of questionable value.” Furthermore, he believes that lack of litigation over method patents shows that such patents possess an “insignificant” role in medicine. Professional recognition and clinical success constitute sufficient motivation for inventors. In Noonan’s view, “available evidence strongly indicates that a patent is usually not an essential pre-requisite to the development of a new procedure (in contrast to the development of new drugs or devices, or new methods of using them).”<sup>67</sup> Noonan distilled his point in the following passage:

“The ethical question about procedure patents is whether the benefit of these patents in promoting innovation is great enough to justify the burden of interfering with a physician’s ability to choose the best known treatment for every patient. The historical record shows procedure patents have been irrelevant to medical progress. Absent compelling evidence of the importance of procedure patents to medical

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<sup>64</sup> Hearing, p. 61.

<sup>65</sup> Hearing, pp. 66-7.

<sup>66</sup> Hearing, p. 66.





innovation, the social cost of procedure patents outweighs their practical and ethical impositions.”<sup>68</sup>

Noonan finds medical method patents to be “ethically troubling and unimportant to medical progress.” He advocated banning them without impeding other forms of patent protection.

Skillington believed the same problems with H.R. 1127 would emerge with Frist’s proposal. In Skillington’s view, if the problem was collecting prior art and having information accessible, the problem could be solved administratively.<sup>69</sup> If the law was correct and the problem was with how the PTO was applying the law, it could also be dealt with internally.

Skillington offered a number of remedies for the problems raised by proponents of H.R. 1127.<sup>70</sup> He proposed to conduct hearings on how PTO practices can be modified to better meet the problems of patenting medical methods. He believed hearings would lead to identification of less drastic measures than H.R. 1127. He noted that other bills currently before the Subcommittee would make it easier to challenge patents at the PTO and would require the PTO to publish patent applications no later than 18 months after the filing date. Skillington supported the application of the experimental use doctrine to address the problem of lack of peer review. He noted that this remedy was discussed at a 1994 PTO hearing on patents in biotechnology. Finally, Skillington suggested reexamination as a less expensive venue than litigation to show that prior art invalidates a patent.

### Exploring a Non-Legislative Remedy

On May 2, 1996, the PTO held hearings on patent protection for therapeutic and diagnostic methods.<sup>71</sup> The purpose of the hearing was to discuss if the problems raised by proponents of H.R. 1127 and S. 1334 could be remedied administratively, rather than legislatively. Discussing ethics was explicitly excluded. In a letter to the PTO, Representative Moorehead asked the hearing participants to discuss the

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<sup>67</sup> Hearing, p. 66.

<sup>68</sup> Hearing, p. 66.

<sup>69</sup> Hearing, p. 37.

<sup>70</sup> Hearing, pp. 30-32.



PTO's resources, application of patentability standards, and reexamination venue; the publication of patent information; experimental use; and the foreign experience in medical method patenting.<sup>72</sup> Witnesses echoed themes expressed in the Congressional subcommittee hearing on H.R. 1127. The issue of the uniqueness of medical methods arose again, but this time it was set in the context of the patenting experience of biotechnology and computer software. Once again, the cultures of the medical and patent law communities clashed as each held a different view of the nature of medical procedure innovation.<sup>73</sup>

Critics have said the PTO is incapable of reviewing medical method patent applications properly. However, one witness stated that a PTO decision is just an approximation of a litigation outcome.<sup>74</sup> Robert Portman, one of Singer's attorneys, stated that examiners cannot understand prior art or the level of ordinary skill across all medical specialties and therefore cannot review medical method applications appropriately.<sup>75</sup> Richard Burgoon, senior patent counsel for Cephalon, Inc., countered that patentability standards are rarely misapplied. He believes the problem usually stems from not finding relevant prior art because of a genuine mistake on the part of the examiner or because of error or malfeasance on the part of the inventor.<sup>76</sup> Many witnesses identified inability to locate publications and foreign patents as problematic.<sup>77</sup> Portman raised the problem of inaccessibility of medical procedure knowledge because much of it is unpublished and created in physicians' offices.<sup>78</sup> Donald Dunner, Chair of the ABA Section on Intellectual Property Law, said there was no proof of this.<sup>79</sup> Witnesses suggested the PTO gain access to electronic journal databases and medical videos (e.g. ASCRS films). Considering that Pallin was initially denied publication of his chevron incision, Burgoon suggested the medical profession might reassess its

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<sup>71</sup> "Public Hearings on Patent Protection for Therapeutic and Diagnostic Methods," May 2, 1996. Hereafter referred to as "PTO Hearing."

<sup>72</sup> Federal Register Notice, Vol. 61, No. 50, March 13, 1996. Section A of PTO Hearing.

<sup>73</sup> This is a generalization. Dr. Pallin holds a view of the patent system which is similar to that held by many patent attorneys. Robert Portman, one of Singer's attorneys, holds a view similar to that held by many physicians.

<sup>74</sup> Professor Carl Moy for the ABA Section on Intellectual Property. PTO Hearing, p. 27.

<sup>75</sup> PTO Hearing, p. 62.

<sup>76</sup> PTO Hearing, p. 97.

<sup>77</sup> Frank Schaller, President of the Boston Patent Company, an information clearinghouse-type of company believes the root of the problem of accessing information lies in the explosive growth of patent and medical literature. PTO Hearing, p. 53.

<sup>78</sup> PTO Hearing, p. 80.

<sup>79</sup> Dunner letter to PTO, p. 4 in PTO Hearing.



criteria for publication of procedures.<sup>80</sup> To create statutory prior art, the medical community might encourage physicians who have been denied publication to publish through the PTO with statutory invention registration. To improve the quality of examinations, hearing participants recommended hiring physicians and nurses as examiners, assembling physician consultants,<sup>81</sup> using NIH assistance, and instituting a continuing education requirement for examiners (in-house courses and guest lecturers).

There was less agreement on reexamination as a sensible administrative remedy. Portman pointed out that Singer could not have successfully challenged Pallin's patent in a reexamination proceeding because the prior art was mostly unpublished. Deposition testimony, surgical reports, affidavits, and unpublished articles are inadmissible.<sup>82</sup> While changing PTO rules to admit unpublished evidence would appear to solve the problem, Pallin and Burgoon identified the danger in such an act. In a letter to the PTO, Pallin stated that reexamination would open itself to largely anecdotal information,<sup>83</sup> and therefore, as Burgoon pointed out, reexamination would become a judicial proceeding in which the PTO would have to make factual determinations of the credibility of evidence presented.<sup>84</sup>

However, there was little disagreement that the experimental use doctrine could cover the use of a patented medical method for peer review. Likewise, the issue of publishing patent information created little stir as witnesses simply recommended faster issuance and publication of patents.

The topic of foreign experience with medical method patenting revealed a critical discrepancy. Portman stated that over 80 countries ban the patenting of medical procedures, but Professor Carl Moy, representing the Section of Intellectual Property of the American Bar Association, stated that the international community supports such patenting.<sup>85</sup> Dunner provided a possible explanation for this discrepancy by stating that some non-patenting countries may be "free-riding" on innovations developed in patenting countries.<sup>86</sup> Nevertheless, many of the witnesses advised caution in changing U.S. patent law

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<sup>80</sup> PTO Hearing, p. 100.

<sup>81</sup> 4/23/96 Letter from Pallin to PTO in PTO Hearing.

<sup>82</sup> PTO Hearing, pp. 68-9.

<sup>83</sup> 4/23/96 Letter from Pallin to PTO in PTO Hearing.

<sup>84</sup> Burgoon notes that conducting a quasi-judicial proceeding would raise PTO costs. PTO Hearing, p. 102.

<sup>85</sup> See written submission of the Medical Procedure Patent Coalition and the testimony of Professor Carl Moy in PTO Hearing.

<sup>86</sup> 5/17/96 Letter from Dunner to PTO, pp. 7-8. PTO Hearing.



because foreign laws are embedded in different cultures and have arisen under different circumstances. What applies in another country may not apply in the U.S.

A pervasive theme of the hearing was the issue of the alleged uniqueness of medical method inventions. In Portman's view, medical methods are different. They are developed in a cultural tradition of free exchange of knowledge. Patenting would disrupt this tradition and hinder patient care. Medical methods have low innovation costs. Alluding to Pallin's patent, Portman said the PTO issues medical method patents that should never have been issued. However, Dunner noted that unwarranted patents are occasionally issued in every field.<sup>87</sup> Portman and the Medical Procedures Patent Coalition believe the patent system represents a balancing of public policy interests, and in the area of medical method patents, the public interest is best served with an enforcement ban.<sup>88</sup> However, Dunner asserted that not enacting an enforcement ban would serve the public interest by assuring more medical advances in the future.<sup>89</sup> Burgoon asserted that patent applications should never be reviewed with attention to resources expended when he said, "One man's flash of genius may be another man's life long obsession."<sup>90</sup>

Burgoon noted that the biotechnology industry addressed its patenting problems by working within the existing patent system.<sup>91</sup> The industry did not request special protection. The PTO created a separate art unit to review biotechnology applications and hired examiners with molecular biology backgrounds. Consequently, the initial problems in issuing biotechnology patents, as well as computer software patents, have been reduced or alleviated.

Dunner placed the alleged administrative problems of medical method patents in perspective:

"Even with dedication from the PTO, the examination process cannot guarantee a perfect adjudication of every application for patent.

Perfection in the field of therapeutic and diagnostic methods is thus

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<sup>87</sup> Letter from Dunner to PTO, p. 4.

<sup>88</sup> PTO Hearing, p. 79.

<sup>89</sup> Letter from Dunner to PTO, p. 2.

<sup>90</sup> PTO Hearing, p. 94.

<sup>91</sup> PTO Hearing, pp. 94-5.





unattainable. Rather, the goal must be to keep the inherent perfections tolerably small.”<sup>92</sup>

### Legislating the Prohibition on Enforcement

Representative Moorehead, who chaired the hearing on H.R. 1127, believed the problems raised by the patenting of medical methods would likely be resolved administratively.<sup>93</sup> But with little support for H.R. 1127 and no resolution of the problem by July 1996, Representative Ganske attempted to amend the PTO appropriations bill to include a version of the medical method patents prohibition that did not prohibit new use patents.<sup>94</sup> But this amendment never reached the Senate floor. In June 1996, the AMA Board of Trustees met with the Pharmaceutical Research and Manufacturers of America (PhRMA) Board of Directors to resolve differences over the Ganske and Frist bills (H.R. 1127 and S. 1334).<sup>95</sup> In spite of concerns over Trade-Related Aspects of Intellectual Property (TRIPs) under GATT,<sup>96</sup> Senator Frist’s bill was ultimately incorporated into the Omnibus Consolidated Appropriations Act of 1996 and passed as Section 616 of Public Law 104-208 on September 30, 1996.

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<sup>92</sup> 5/17/96 Letter from Dunner to PTO, p. 3.

<sup>93</sup> *Congressional Record* (House), p. H8277 (July 24, 1996) in Mossinghoff, G. “Remedies Under Patents on Medical and Surgical Procedures,” *Journal of the Patent and Trademark Office Society*, November 1996, p. 791.

<sup>94</sup> Mossinghoff, pp. 791-2.

<sup>95</sup> The parties composed a section of “Legislative Intent” which defined the scope of the legislation in more detail than the text of the bills. Mossinghoff, p. 795.

<sup>96</sup> Some senators opposed Frist’s bill because Article 27(1) of TRIPs calls for no discrimination against any field of technology in the realm of patentability. However, Article 30 states that member nations may establish “limited exceptions.” Mossinghoff, pp. 795-7.



## XII. *Markman*

While Congress was choosing among H.R. 1127, S. 1334, and no legislative action, *Pallin v. Singer* took a surprising turn. The recently rendered *Markman* ruling proved to be a key turning point in *Pallin v. Singer* for it allowed the defense to take what Pallin's attorney called "a second bite at the apple."<sup>1</sup> In a letter dated November 15, 1995, Singer's attorney, George Neuner, informed Judge Sessions, who had succeeded Judge Billings, that the Court of Appeals for the Federal Circuit (CAFC), which handles appeals of patent cases, had "recently issued a decision that substantially changes the procedure with respect to jury trials in patent cases." Neuner cited *Markman v. Westview Instruments*, an April 1995 case in which the CAFC held that "the interpretation and construction of patent claims, which define the scope of the patentee's rights under the patent, is a matter of law exclusively for the court."<sup>2</sup> Thus, disputes over the meaning of patent claims were to be decided without a jury. Because the Court of Appeals for the Federal Circuit is a higher court than the U.S. District Court in Vermont, the District Court was bound to follow CAFC precedent. However, Judge Billings had already rejected the defense's motion for summary judgment thereby sending the case to jury trial.

Anticipating this problem, Neuner cited two cases which had already used the *Markman* precedent. In one case, the court reconsidered a summary judgment motion for patent invalidity and non-infringement which had been denied because of a dispute over meaning of phrases in patent claims.<sup>3</sup> In the second case, the court held a two-day hearing to interpret and construe claims (a "*Markman* hearing").<sup>4</sup> In one stroke, Neuner attempted to redirect the case away from a jury trial and towards a *Markman* hearing.

On November 27, 1995, Judge Sessions held a status conference to decide if a *Markman* hearing should be held in *Pallin v. Singer*. Neuner suggested that an evidentiary hearing would yield economic disposal of the case and would guide the court in determining which issues to resolve with a trial jury, if a trial were required. Pallin's attorney, John White, stated that a hearing was unnecessary because there was no dispute over the claims. In his view, the defense was broadly interpreting Pallin's claims merely "to

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<sup>1</sup> Pallin interview, p. 17.

<sup>2</sup> *Markman v. Westview Instruments, Inc.* 52 F.3<sup>rd</sup> 967 (Fed. Cir. 1995) (en banc).

<sup>3</sup> Cites *American Permahedge, Inc. v. Barcana, Inc. and National Metal Industries, Inc.*, 1995 U.S. Dist. LEXIS 15838 (S.D.N.Y.).



scrape in prior art.”<sup>5</sup> Judge Sessions was not swayed by White’s effort.<sup>6</sup> However, Sessions did recognize, in retrospect he points out, that Judge Billings had misunderstood the law when he ruled on the motion for summary judgment. Billings had correctly identified factual disputes in the case but had not referred them to the proper forum for resolution. White was forced to concede that the *Markman* precedent applied to *Pallin v. Singer*.

Sessions was well aware that holding a *Markman* hearing would grant the defense a second opportunity to make its case for summary judgment – “a second bite at the apple.” Neuner agreed but said this was merely an effect of applying the law. Sessions remarked that summary judgment had been raised a second time in a number of cases in the Second Circuit. White declared his intention to file for summary judgment also. In the interests of expeditiously disposing of the case, Sessions asked that all expert witnesses be present at the hearing.

The hearing was scheduled for March 13-15, 1996,<sup>7</sup> but in early January, the plaintiff requested a rescheduling to March 26-28 “to enable the development of settlement discussions between the parties initiated during the last week of December 1995, and presently ongoing.”<sup>8</sup> At the same time, White informed Judge Sessions that the Supreme Court had just heard arguments in an appeal of the *Markman* ruling and pointed out that if the lower court’s decision were overturned, the hearing in *Pallin v. Singer* would be rendered moot.<sup>9</sup> Thus, the *Markman* precedent stood to be overturned which would swing the pendulum back to the plaintiff and prevent a “second bite at the apple.”

### *Markman Revisited*

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<sup>4</sup> Cites *Elf Atochem v. Libbey-Owens-Ford Co.*, 894 F.Supp. 844 (D.Del. 1995).

<sup>5</sup> 11/27/95 status conference, p. 4 in Opposition of Dr. Singer and the Hitchcock Clinic to Plaintiff’s Motion to Extend the Schedule and Reopen Discovery (filed 2/23/96).

<sup>6</sup> White’s effort seemed to demonstrate the existence of a dispute in which the plaintiff was narrowly interpreting claims and the defense was broadly interpreting claims. 11/27/95 status conference, pp. 8-9 in Opposition of Dr. Singer and the Hitchcock Clinic to Plaintiff’s Motion to Extend the Schedule and Reopen Discovery (filed 2/23/96).

<sup>7</sup> A two-day hearing, with a third day, if necessary.

<sup>8</sup> Notice of Hearing for U.S. District Court (filed 11/28/95); Plaintiffs’ Unopposed Request to Modify Briefing Schedule and Hearing Date (filed 1/17/96); Notice of Hearing (filed 1/23/96).

<sup>9</sup> Plaintiffs’ Unopposed Request to Modify Briefing Schedule and Hearing Date (filed 1/17/96), p. 2.



John White was not going to wait for the Supreme Court. Although White had previously conceded to Judge Sessions' conclusion that *Markman* was applicable to *Pallin v. Singer*, in February 1996, White filed opposition to holding a *Markman* hearing. He asserted that *Markman* was not applicable because the defense, in that case, had submitted a summary judgment motion aimed at the issue of infringement, whereas Singer had submitted a motion aimed at patent validity. In the words of the plaintiff's attorneys:

“Defendants have improperly bootstrapped a second bite at the validity apple by providing this Court with an erroneous view of what Markman set forth and then proceed to seek a second opinion on the same issues. . . . In contrast to the issue of infringement (wherein an assessment of the meaning of the claims can be determined according to the specification of the patent, the file history, and expert assistance) the issue of patent validity is fraught with factual determination.”<sup>10</sup>

White believed that determining infringement was an issue of law. That is, the judge and counsel should be able to determine the nature of an invention by looking to the patent, its application history, and expert witness testimony. The Court compares this with the nature of the infringing invention and then applies the law. However, in White's view, assessing patent validity is an issue of law and factual determination. Presumably White was supporting his argument with the idea that the Court and counsel would have to assess the patentability of the patented invention by determining the utility of the invention (utility), prior art in the field (novelty), and the level of ordinary skill and knowledge in the field (nonobviousness), which could very well require a jury. After factual determination, the Court would apply relevant law. Because the defense's motion for summary judgment in *Pallin v. Singer* requested a ruling of patent invalidity

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<sup>10</sup> Motion to Extend Time for Response and Reopen Discovery, or, in the Alternative, to Exclude Evidence of Dr. Gills & William H. Ausmus (Filing date not stamped on document; but likely to be 2/13/96), pp. 3-4.





rather than a ruling of no infringement, the plaintiff saw the *Markman* hearing as an opportunity for the defense to have the Court reconsider its previous decision.

The defense begged to differ. It questioned why the plaintiff did not raise its argument opposing the application of *Markman* at the November 1995 status conference. The defense flatly rejected the plaintiff's view that infringement is a matter of law and patent validity is a matter of fact. It said that infringement is an issue of law only when the basic facts are not disputed. Furthermore, the defense held that the relevance of *Markman* to infringement and patent invalidity is the same. The defense demonstrated the relationship between infringement and invalidity when it cited a textbook in saying that what infringes, if it occurred after the invention, will anticipate, if it occurred before the patented invention. Finally, the defense stated that *Markman* does not suggest that summary judgment is applicable only to cases of infringement. According to the defense, the "issue considered on appeal in *Markman* was simply whether claim construction was a legal issue for the Court."<sup>11</sup>

The plaintiff's opposition appeared to be a last-ditch effort to redirect the case to a jury trial. White was correct in distinguishing infringement and invalidity, although in this case, the two are tied when one considers that Singer's invention was originally thought to have been developed after Pallin's invention. Furthermore, even an infringement suit would require factual determination in establishing the nature of the infringing invention. The parties in *Pallin v. Singer* disputed claim interpretation and construction, thus requiring an evidentiary hearing which Judge Billings did not provide as a matter of law. There would be a "second bite at the apple" barring an adverse decision by the Supreme Court.

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<sup>11</sup> Opposition of Dr. Singer and the Hitchcock Clinic to Plaintiff's Motion to Extend the Schedule and Reopen Discovery (filed 2/23/96), p. 12.



### XIII. Third phase of judicial proceedings

#### Taking a Second Bite at the Apple

In this phase of the case, the defense assembled a new legal team<sup>1</sup> which introduced new evidence and enhanced old evidence. When the defense filed a motion for summary judgment the second time around, the noose around Pallin's patent tightened. The defense attacked Pallin's credibility and continued to campaign aggressively to invalidate his patent. Unexpectedly, it was discovered that Singer had never infringed Pallin's patent, even if Pallin's chevron were the first sutureless incision to be invented. As the case moved forward, the arguments became crisper as both sides distilled legal points to the essentials, and as issues of patent interpretation, prior art, and nonobviousness merged (See Core Arguments C).

At the outset of its memorandum in support of summary judgment, the defense expressed its belief that Pallin's patent should not be enforced on both an ethical and legal basis:

“This is a deeply troubling lawsuit. Regardless of one's view of the wisdom of surgical method patents – and their potential chilling effect on the teaching and use of surgical techniques that improve the health of patients – plaintiff's attempt to enforce patent claims in this case has no basis in fact or law.”<sup>2</sup>

At this point in the case, Pallin had to worry less about ethical opposition and more about the ability of his patent to stand on its own merits.

#### *Credibility: Rescuing Gills and Tarnishing Pallin*

Gills' testimony to the effect that he “estimated, guesstimated” incision distances had, in part, cost the defense a favorable summary judgment ruling by Judge Billings. Now, Gills was attempting to shore

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<sup>1</sup> Robert Portman and Kit Pierson of Jenner & Block in Washington, DC.



up that weakness.<sup>3</sup> While defending his practice of estimating incision distances, Gills now claimed having measured incision distances that fell in the range specified by the Pallin patent:

“From March 19, 1990 to April 17, 1990, I performed 375 surgeries using the inverted V. During this period, I made the incision so that the apex or tip of the inverted V was located in the range of 1.5-4 mm above (i.e., posterior to) the limbus. Many of these procedures were between 1.5 and 3 mm from the limbus. Like most other experienced cataract surgeons, I would usually estimate this distance rather than measure it with an instrument. An experienced surgeon can estimate the appropriate distance to within 0.5 mm without difficulty. However, I would measure the distance exactly if the results were being used for a controlled clinical study, which was the case with many of the surgeries that I performed during this period.”<sup>4</sup>

Attempting to salvage Gills’ credibility, Gills’ surgical assistants submitted declarations to support his current statements. Sherry Gillis, who like Gills had previously stated that incisions distances were estimated, now echoed Gills’ assertions.<sup>5</sup> William Ausmus, who had worked with Gills for 15 years, introduced what was in theory decisive evidence that Gills had made an inverted V with an apex less than three millimeters posterior to the limbus.<sup>6</sup> Appended to Ausmus’ declaration were an operative report, a photograph of Patient 208120, and a patient list showing that no sutures were used on this patient. Ausmus had examined the eyes of Patient 208120 postoperatively:

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<sup>2</sup> Defendants’ Memorandum Addressing Markman Issues and in Support of Motion for Summary Judgment (filed 2/13/96), p. 2.

<sup>3</sup> Declaration of James Gills, M.D. in Defendants’ Memorandum Addressing Markman Issues and in Support of Motion for Summary Judgment (filed 2/13/96)

<sup>4</sup> Defendants’ Memorandum Addressing Markman Issues and in Support of Motion for Summary Judgment (filed 2/13/96), pp. 2-3.

<sup>5</sup> Declaration of Sherry Gillis.



“I was able to see the scar from the inverted V very clearly. I measured the distance from the apex of inverted V to the limbus using a metric ruler. This distance was clearly less than 3 millimeters.”<sup>7</sup>

The centerpiece of the defense’s prior art argument solidified. Unless the plaintiff could reject this evidence, Pallin’s patent would be invalidated by dint of prior art.

Turning to Pallin, the defense once again raised the issue of inequitable conduct at the PTO. It also painted an image of Pallin as interested only in money. The defense stated that Pallin had been building upon Steven Siepser’s work and knew of the written disclosures of other ophthalmologists regarding their sutureless incisions. But, he did not report this information to the PTO.<sup>8</sup> The defense did not provide detail, but an examination of the evidence supports its point.

In the body of his November 1990 letter to the editor of the *Journal of Cataract and Refractive Surgery* -- a letter which was accepted in lieu of his original article submission -- Pallin cites articles on the work of Siepser (“Radial Incision Helps Reduce Astigmatic Forces,” *Ocular Surgery News*, March 15, 1990, p. 1.), Kondrot (“Self-Sealing Tunnel Incision Facilitates Patient Recovery,” *Ophthalmology Times*, June 15, 1990, p. 1), and McFarland (“Surgeon Undertakes Phaco, Foldable IOL Series Sans Sutures,” *Ocular Surgery News*, March 1, 1990, p. 1).<sup>9</sup> Pallin performed his first chevron incision on April 19, 1990. He says he submitted an article for publication the following day. At the time, he says he had heard only of the sutureless incisions of Siepser and McFarland. According to Pallin, only Siepser published in a peer-reviewed journal, and McFarland did not describe his incision.<sup>10</sup> Pallin submitted his patent application on June 28, 1990. While Pallin may not have known of Kondrot’s and McFarland’s work at the level of a peer-reviewed article (or even a news article), at the time of submitting his patent application, he did know of Siepser’s sutureless incision work at the level of a peer-reviewed article. He probably should have listed

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<sup>6</sup> Declaration of William Ausmus.

<sup>7</sup> Declaration of William Ausmus, p. 2.

<sup>8</sup> Defendants’ Memorandum Addressing Markman Issues and in Support of Motion for Summary Judgment (filed 2/13/96), p. 19.

<sup>9</sup> Pallin, S. “Letter to the editor: Chevron Incision for Cataract Surgery,” *Journal of Cataract and Refractive Surgery*, 16: 779-81.

<sup>10</sup> Pallin interview, p. 3, 7.





Siepser's work in his patent application, as a matter of law. Pallin claimed throughout the court case and in his articles on the chevron incision that his incision went beyond the work of others and therefore constituted a true invention. If he was confident about this, then he would know that informing the PTO of Siepser's work would not affect the patentability of his invention. Perhaps he was not so confident. Furthermore, as his patent application was being reviewed, he undoubtedly read of the sutureless incisions of others. If these incisions had been developed before April 19, 1990, which was definitely the case for the incisions of Siepser and McFarland (by Pallin's own citation of articles published in March 1990), Pallin had an obligation to report them even after submitting his patent application, if they were relevant to patent examination. But perhaps Pallin did not think this prior work was relevant. This argument might work with Siepser's incision but not with McFarland's incision.<sup>11</sup> Nevertheless, in the defense's view, "from reading plaintiff's patent disclosures, one would not even know that sutureless cataract surgery had ever been performed. . ."<sup>12</sup> The defense wrote that Pallin's failure to disclose "the most relevant prior art" makes it easy to meet the standard of clear and convincing evidence for invalidating a U.S. patent.<sup>13</sup>

The defense then turned to Pallin's motivations in patenting the chevron incision technique. According to the defense, in the year prior to filing a Complaint against Singer, Pallin had tried to donate his patent to the American Society of Cataract and Refractive Surgery.<sup>14</sup> Such beneficence would have apparently earned him a tax deduction. However the ASCRS refused the offer because it was ethically opposed to patents on surgical techniques, and it believed Pallin's patent was invalid. The defense pointed out that Pallin could have donated his patent to the public at any time but instead chose to sue Singer and the Hitchcock Clinic. This suggests Pallin was primarily interested in money.

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<sup>11</sup> Siepser's incision was a radial incision and therefore quite different from the chevron (See Chart on Incision Shapes). McFarland's incision, on the other hand, was a straight line incision, and a straight line is closer in shape to an obtuse angle chevron or minimal arc curvilinear incision.

<sup>12</sup> Defendants' Memorandum Addressing Markman Issues and in Support of Motion for Summary Judgment (filed 2/13/96), p. 19.

<sup>13</sup> Defendants' Memorandum Addressing Markman Issues and in Support of Motion for Summary Judgment (filed 2/13/96), p. 38, Footnote 51.

<sup>14</sup> Pallin filed his Complaint against Singer and the Hitchcock Associates of Randolph on July 6, 1993. Defendants' Memorandum Addressing Markman Issues and in Support of Motion for Summary Judgment (filed 2/13/96), p. 20, Footnote 23.



The defense continued to portray Pallin in a dark light as it once again highlighted the contradictions, inconsistencies, and ambiguities in Pallin's statements.<sup>15</sup> The items raised by the defense were consistent with a plaintiff strategy of first broadening the scope of the patent when it was believed the chevron was the first sutureless incision of its kind, and then narrowing the scope of the claims when it was discovered that other surgeons had developed sutureless incisions before the first chevron incision.<sup>16</sup>

### *Reconciling Suturelessness and Suture Use*

The defense described an apparent internal inconsistency in Pallin's patent which could constitute grounds for invalidation (See Table – Contentious Patent Text, and Core Arguments C). The defense wrote that the plaintiff was trying to use the notion of suturelessness in the patent preamble (presumably referring to the abstract) to assert that the invention is sutureless when descriptive text (non-claim text) of the patent document specifies that a suture can be used and when Pallin himself testified that a suture can be used with large lens implants.<sup>17</sup> The defense noted that if a surgeon follows what the patent teaches regarding use of a suture, then he has practiced the claimed invention. If the teaching in the patent does not yield the invention (failure to disclose/enable), then the patent is invalid by law. The issue can be distilled to the simple question: how can a sutureless method have a patent specification that permits using a suture?

The issue arose because the plaintiff was trying to escape the prior art of Singer. Singer had used single sutures with his frown incision wounds. Because Singer's wound closures were not sutureless, the plaintiff claimed that Singer had not practiced Pallin's patented incision method. However, Singer had used a 6 millimeter IOL in his surgeries. The descriptive text of the Pallin patent specifies that a surgeon

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<sup>15</sup> Defendants' Memorandum Addressing Markman Issues and in Support of Motion for Summary Judgment (filed 2/13/96), pp. 21-9.

<sup>16</sup> The defense points out again that early on in the case, Pallin stated that straight line incisions fall under the purview of his patent, whereas later in the case, Pallin denied inclusion of straight line incisions in his patented invention. Pallin had also previously deemed the chevron equivalent to the frown because he said "virtually every incision, at some point in the incision, will look like a frown because of the stretching and manipulating." Pallin's previous statements were now constraining him. Defendants' Memorandum Addressing Markman Issues and in Support of Motion for Summary Judgment (filed 2/13/96), p. 28.

<sup>17</sup> Defendants' Memorandum Addressing Markman Issues and in Support of Motion for Summary Judgment (filed 2/13/96), pp. 31-35.



inserting a 6 millimeter diameter optic through a larger incision may occasionally require a single suture for complete sealing.

Did Singer practice Pallin's patented invention? The answer is not clear but lies in the relationship between patent claims and specifications (non-claim text). Though patent claims are central to a patent case, specifications outside the claims can narrow their scope. Thus, there would appear to be an internal inconsistency in Pallin's patent. None of the patent claims possesses a limitation that incision wounds must be sutureless. As a matter of fact, the claims do not discuss sutures or even wound closure. The "Description of Drawings" section that precedes the claims section discusses the condition under which a suture can be used. Thus, the defense points to the concept of suturelessness, which is not in the claims, and then poses it against the notion of using a suture under a specific condition, which is also not in the claims. While the defense appears correct in identifying an inconsistency in the content of Pallin's patent, it is trying to have it both ways – create a contradiction by juxtaposing an idea from the preamble with an idea that it incorrectly asserts is in the patent claims. Thus, if it wants to discard Pallin's attempt to include a preamble concept in the claims, then it should discard its attempt to include the patent's teaching of suture use in the patent claims. If one looks solely at the claims, ignoring the rest of the patent, then it would appear that Singer practiced the incision specified in the patent. However, he used a suture, which while not prohibited by the claims, is contrary to the spirit of the invention. Thus, it would appear that Singer did not practice the invention, for it would appear he needed a suture to help seal the wound or to add a measure of safety in case the wound reopened.

### *Solidifying Prior Art*

On the prior art front, additional details about the incisions of McFarland, Ernest, Gills, and Singer strengthened the defendants' case. Once again, the battles were fought in the trenches between two sides of ophthalmologic experts, but the technical points and their relationship to key legal arguments were becoming clearer.



Gills reiterated that he had performed his inverted V incision before Pallin performed the chevron incision. Responding to the plaintiff's charge that he did not disclose his invention, Gills stated that he had presented the inverted V incision in about 30 lectures after March 1990.

Singer wrote that his first and second frown incisions, performed on March 20 and March 27, 1990 respectively, met the claims at issue in the case. Both were located two millimeters from the limbus. Singer stated that he used a single suture for both incisions as taught at column 4, lines 41-45<sup>18</sup> of Pallin's patent for larger lens implants. Finally, Singer stated that he made a scleral tunnel that widened "in a funnel shape" as it neared the anterior chamber.<sup>19</sup> Singer also emphasized that he had disclosed his technique in *Ocular Surgery News*, a videotape for the third issue of 1990 for the *Audiovisual Journal of Cataract and Implant Surgery*,<sup>20</sup> and other journals and symposia. Singer corrected the plaintiff's assertion that he had eventually omitted a suture because he began to use a tunnel length to width ratio greater than one.<sup>21</sup> Singer said he omitted a suture in 1991 because he began to create an internal corneal seal with his incisions.

Just as the plaintiff had charged that Singer adopted Pallin's tunnel length to width ratio, the defense now asserted that Pallin incorporated Singer's corneal tissue component, as possibly shown by Pallin's deposition statements:

"A. [Pallin:] It's just easier to avoid bleeding if you stay out of the chamber angle and come a little bit into the cornea. My first series of – I don't remember – 600 or 800 cases – they were all done through the angle and we had a few hyphemas, which is post-operative blood in the

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<sup>18</sup> Lines 41-45 of column 4 read: "Further, even larger lens implants of up to 6 millimeters in diameter may be inserted through larger incisions...although a single suture may occasionally be required for complete sealing."

<sup>19</sup> Pallin has used the word "funnel" with respect to the scleral tunnel. Either the word is commonly used or Singer was attempting, consciously or subconsciously, to show his technique was exactly what Pallin and his patent teach.

<sup>20</sup> Singer narrates a video demonstration of his "frown incision with single-stitch closure" that allows insertion of up to 7 millimeter optics. The video was used as a court exhibit.

<sup>21</sup> Singer declared: "I later reduced the width of the incision, but it remained greater than or equal to the length of the scleral tunnel. Moreover, Dr. Pallin has no basis for making a contrary statement because he has never seen me perform surgery." Declaration of Jack Singer, p. 6, Footnote 3.





eye, that we had to wait for clearing. And that was generally the experience of others, as well. // Q (Neuner). I see. Then you started to go just slightly into the cornea after that? // A. Basically. Of course, the incision may be three to five millimeters wide as it enters into the anterior chamber. Some of it may be at an angle. Some of it may be in the cornea.”<sup>22</sup>

The angle Pallin refers to is the tissue at the angle between the iris and the cornea which is in the anterior chamber. A hyphema is a form of internal bleeding in the eye. The presence of a hyphema does not imply external leakage, and it is external leakage which is central to the notion of self-sealing. The defense may be overextending Pallin’s words to fit its argument, but it is possible that Pallin might have been unintentionally or unknowingly creating internal corneal lips which prevented hyphemas. However, the defense offered no proof of this.<sup>23</sup>

The defense constructed a compelling argument for invalidating the patent by showing that the incisions of Gills and Singer, as well as the incisions of McFarland and Ernest (if Pallin’s patent is considered to cover straight-line incisions), anticipated the chevron incision. Particularly damaging for Pallin was that Gills had used the same geometry and location of the chevron incision. And, the defense improved Gills’ previous image as imprecise while stating that even Pallin estimated incision distances.<sup>24</sup> Finally, the defense emphasized that Gills, Singer, McFarland, and Ernest had publicized their incision techniques via lectures and journals and had also met the legal standard of disclosure. The defense cited a recent case in which the court held that the use of a device in a hospital constitutes public disclosure even though the operating room is not available to the public.<sup>25</sup>

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<sup>22</sup> 6/13/94 Deposition of Samuel Pallin, p. 60. Cited in Defendants’ Memorandum Addressing Markman Issues and in Support of Motion for Summary Judgment (filed 2/13/96), pp. 2-3.

<sup>23</sup> Creating a corneal lip requires beveling the incision or dimpling the cornea, neither of which is indicated in the cited deposition testimony.

<sup>24</sup> From the same deposition of Pallin, it is discovered that Pallin measures incision distances from the posterior limbus, that is, the outer circumference of the limbus.

<sup>25</sup> Defense cites 3M v. Research Medical Inc. The court held that the use of a device in a hospital constitutes public disclosure even though the operating room is not available to the public. The court found that the device was used in its intended manner. Regarding *Pallin v. Singer*, any cataract surgery



While the defense attacked the validity of Pallin's patent by dint of prior art, it also stood poised to render moot Pallin's charge of infringement. One of the witnesses for the defense had apparently discovered that Singer had modified his incision distance to less than 1.5 millimeters around January 1992, the same month Pallin's patent was issued.<sup>26</sup> If Singer did not place his incisions in the 1.5 to 3 millimeter range specified by Pallin's patent, then he did not infringe. The defense appeared to have the best of both worlds in that it mounted a strong argument of patent invalidity by dint of prior art, and it stood to dismiss Pallin's initial charge of infringement.

*Vigorously campaigning to invalidate – Expert Declaration of Dr. Howard Fine*

The noose around Pallin's patent tightened as the defense aggressively tried to corner Pallin on the fronts of internal consistency of the patent, prior art, and obviousness. The aggressive approach is exemplified by Dr. Howard Fine,<sup>27</sup> one of the defense's expert witnesses. He argued many points but only makes one convincing argument. He addressed mostly issues of patent interpretation. Fine takes the approach to the extreme with his hypercritical attack of the Pallin patent. In his zeal to defeat Pallin's patent, he reaches for any available argument, any available hair to split – hairs that are esoteric and in defiance of common sense and are therefore peripheral, at best, and foolish and unfair, at worst. However, analyzing Fine's criticisms illuminates the nature of Pallin's invention and patent, and the essence of patent adjudication.

Fine confines his testimony to critiquing Pallin's patent.<sup>28</sup> In Fine's opinion, "the patent fails to teach the invention being claimed, and it would be extremely difficult, if not impossible to replicate the result sought by Dr. Pallin without much clearer information." Yet, the defense finds the information clear enough to assert that Gills' inverted V incision met the claims of the Pallin patent.

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incision technique, if used in its intended manner, would be used in an operating room which is not open to the public. See Defendants' Memorandum Addressing Markman Issues and in Support of Motion for Summary Judgment (filed 2/13/96), p. 39.

<sup>26</sup> The Patent and Trademark Office issued Pallin's patent (U.S. Patent #5,080,111) on January 14, 1992. See Singer interview, p. 3 and Defendants' Memorandum Addressing Markman Issues and in Support of Motion for Summary Judgment (filed 2/13/96), p. 17, Footnote 16.

<sup>27</sup> A board-certified ophthalmologist with over 25 years experience, Director of the Oregon Eye Institute and a Clinical Associate Professor of Ophthalmology at Oregon Health Sciences University.

<sup>28</sup> That is, he does not buttress others' incisions as prior art, defend Gills, or discuss obviousness.



Fine asserts that the phrase “substantially self-sealing” is not used in the art and then proceeds to engage in circular logic:

“Claim 1 begins with a general reference to a “substantially self-sealing” episcleral incision. This is not a term that is used in the art or defined in the patent. It is clear that the incision being described is not self-sealing – it is something short of that. It is also clear that in at least some circumstances, a single suture can be used in connection with the incision.”

If the incision being described is “something short” of self-sealing, then by necessity, it would have to be ‘partially self-sealing’, ‘almost self-sealing’, or perhaps ‘substantially self-sealing.’ And Pallin happens to use this latter phrase. Fine creates a contradiction by implying that the patent professes a purely self-sealing incision (although Pallin might have publicly claimed such) and then proceeding to interpret the patent as describing something short of a purely self-sealing incision.

In the spring of 1990 when the frequency of sutureless incisions was on the rise, terms for the concepts of self-sealing, suturelessness, and other elements of these new incision techniques may not have been standardized. However, Fine’s point is well taken because “self-sealing” and the concept of suturelessness, dating back to the earliest cataract surgery incisions, were familiar to ophthalmic surgeons. To Pallin’s benefit, perhaps he simply reported what he observed in practice – that most, but not all, chevron incisions self-sealed. An analogy might exist in patented pharmaceuticals and medical techniques. These inventions may not completely eliminate disease in a patient, because each patient’s disease severity, receptivity to intervention, and overall situation are different. One could look hypothetically to coronary artery balloon angioplasty, where a catheter is inserted into a clogged heart vessel and a balloon at the tip of the catheter inflates, leading to rupturing and clearing of clots and atherosclerotic plaques. The amount of blockage cleared will differ with different patients and with different physicians’ operating skills. In many cases, less than 100% of the blockage will be removed. One might then write a patent on balloon



angioplasty which states that the technique is “substantially clearing.” The same reasoning would apply to drugs which dissolve clots and atherosclerotic plaques.

Fine states that a person skilled in the art who read the patent would be uncertain when a substantially self-sealing incision had been achieved. One could raise the question of whether “substantially” denotes that a substantial portion of the wound tissue edges will self-seal or denotes that most incisions will self-seal. Fine seems to believe it is the former denotation, although he uses the concept of wound leakage as a proxy for self-sealing of tissue edges (that is, leakage will result when the wound edges are not sealed). It seems that the patent is saying that wounds will always self-seal (achieve water-tightness and suturelessness) unless a large wound (for inserting a lens implant up to 6 millimeters) is being used in which case a suture might be required for complete sealing. The plaintiff believes “substantially self-sealing” is defined in the patent, referring to col. 4, lines 9-16:

“The configurations wherein linear portions. . .of incision 22a [the chevron-shaped incision] and lateral portions...of incision 22b [the curvilinear incision] extend laterally away from the curvature of limbus. . .enable incisions 22a and 22b to be **substantially self-sealing**. When eye. . .is inflated following surgery, the force vectors acting on incision 22a and 22b become **water-tight and require no sutures** for sealing.”<sup>29</sup> (Emphasis mine)

However, as the defense repeatedly pointed out, the patent also allows for the use of a suture in a specific situation:

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<sup>29</sup> U.S. Patent #5,080,111, col. 4, lines 9-16.





“even larger lens implants of up to 6 millimeters in diameter may be inserted through larger incisions...although a single suture may occasionally be required for complete sealing.”<sup>30</sup>

If the Pallin patent states that a suture may “occasionally” be necessary for “complete sealing” of a larger wound, then one can deduce that the patent considers smaller incisions to have achieved “complete sealing.” Thus “substantially” would appear to denote that most incisions achieve complete sealing (the second denotation above).<sup>31</sup> And it can be inferred that large incision size is the key determinant of the occasional occurrence of something that is less than completely self-sealing. Pallin does not define “substantially self-sealing” explicitly, but it appears one can deduce the definition of the phrase from patent text.

Fine goes on to write that Pallin’s patent does not provide a reference point on the limbus from which to measure incision distances. While his remark is correct, it appears to be overcritical and at odds with general practice in the field. Fine writes:

“The patent provides no explanation, however, of the appropriate reference point in the limbus. This is important because “the limbus” is a very imprecise term. That is particularly true at the border of the sclera and the limbus, where the limbus can be uneven and cloudy. Because of this, some surgeons use either the middle of the limbus or the anterior edge of the limbus as the reference point for measuring distance from the limbus. Others use an approximation of the border between the sclera and the limbus (i.e., the posterior edge of the limbus) as the measuring point. The patent again provides no guidance concerning this, apparently leaving it up to the surgeon to decide. This

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<sup>30</sup> U.S. Patent #5,080,111, col. 4, lines 41-45.



means, however, that the range specified in the patent should be understood as an approximation.”<sup>32</sup> (See Figure 1 for “Second Phase of Judicial Proceedings” – Gills’ Issue of Measurement Reference)

It turned out that Pallin measured incision distances from the posterior limbus (the outer circumference of the limbus).<sup>33</sup> Fine correctly points out that Pallin does not specify a precise reference point from which to measure. Pallin refers to the limbus generically. But, Fine also refers to the limbus generically in a 1991 article he wrote; however, he does designate the anterior edge of the corneal vascular arcade as a reference point for incision distances.<sup>34</sup> Fine is presumably referring to the corneal edge of the conjunctival vascular arcade.<sup>35</sup> The vascular arcade is an important landmark for a corneal incision<sup>36</sup>, not a scleral incision. Yet, Fine describes a scleral incision in his article.

Although Fine appears to be meticulous in his measurement of incision distances, his peers fall short by his standards. In the 1991 Supplement of the *Journal of Cataract and Refractive Surgery*, which contains articles by Pallin, Singer, Fine, and others, Pallin refers generically to the limbus; Singer refers to a corneal limbus; Siepser only refers to an incision being posterior to the vascular arcade; Kershner refers to a surgical limbus; and Ernest, a defense witness, and his colleagues refer generically to the limbus. Fine is correct that Pallin does not specify a reference point for measuring incision distances, but both Pallin’s and Fine’s peers also fail to do so. This suggests that it is not an important issue. Furthermore, even if Fine believes it is an important issue for the patent case, then he would stand to potentially hinder the defense. He says the range of incision distance specified in Pallin’s patent should be considered an “approximation.” The Court might proceed with Fine’s assessment but give Pallin the benefit of the doubt

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<sup>31</sup> Although the plaintiff never raises this point, one could speculate that perhaps Pallin used “substantially” to protect himself against physicians who cry foul and claim the invention does not work when they use his invention and occasionally create an incision that leaks.

<sup>32</sup> Fine Declaration, p. 4.

<sup>33</sup> 6/13/94 Deposition of Samuel Pallin, p. 60. Cited in Defendants’ Memorandum Addressing Markman Issues and in Support of Motion for Summary Judgment (filed 2/13/96), pp. 2-3. Ernest tells the court that he believes Pallin’s reference to the limbus is an approximation because Pallin measures from the posterior edge of the limbus while he measures from the mid-point. Declaration of Paul Ernest, p. 12, 16, 21.

<sup>34</sup> Fine, I. H. “Architecture and construction of a self-sealing incision for cataract surgery,” *Journal of Cataract and Refractive Surgery*, 17: 672-6. 1991 Supplement, p. 672.

<sup>35</sup> The cornea is avascular. The conjunctiva however does contain blood vessels.



such that Pallin's patent would cover incision distances 1.5-3 millimeters posterior to the front (anterior) and back (posterior) edge of the limbus.<sup>37</sup> This would effectively increase the range by adding the annular radius of the limbus.

Fine then makes one possibly reasonable and one nakedly crooked attempt to thwart Pallin. Fine attempts to broaden the patent beyond the limits of reason and convention in the art in order to bring it under the purview of prior art:

"Claim 1 describes the shape of the incision as having a central point, with lines on each side of the central point that extend "laterally away from the curvature of said limbus." This description is satisfied by any incision in which the two ends of the incision move farther away from the limbus as they extend from the incision's centerpoint. Because of the curvature of the limbus, this would include an incision facing the limbus, but with a less pronounced arc; a straight line incision; and an incision in which both sides extend in the opposite direction from a line tangent to the limbus." (See Figure 1)

Fine is technically correct to say that the arms of a straight line incision or even of a "smile" (traditional curvilinear) incision with less arc than the limbus move away from the curvature of the limbus (See "Incision Shapes" – Figure 4 for "Ophthalmology for *Pallin v. Singer*"). However, his assessment appears beyond convention in the art. While an intelligent person not in the art of cataract surgery may interpret claim 1 as Fine does, a person in the art would likely interpret claim 1 to cover incisions that curve away from a tangent to the limbus and possibly to cover incisions that follow a tangent to the limbus (i.e. straight line incisions).<sup>38</sup> But Fine's most ludicrous comment follows:

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<sup>36</sup> Weitzman interview, p. 17.

<sup>37</sup> Knowing that Pallin measures from the posterior limbus and assuming an annular radius of 0.5mm for the limbus, this would give an effective range of 1.0-3.0 mm behind the limbus.

<sup>38</sup> See Koch, P. "Structural analysis of cataract incision construction," *Journal of Cataract and Refractive Surgery*, 17: 661-7. 1991 Supplement. This article was the first in the 1991 Supplement issue entitled



“The only material difference in Claims 7 and 22 is the reference to the incision being curvilinear. As a technical matter, this includes all incisions because they are being made on a curved surface. If the Claim language is meant to specify something different from this, it again provides no guidance. The drawings include a curved incision sloping in the direction opposite the limbus. Nothing in the patent, however, suggests that this is the only configuration contemplated. It thus appears to encompass any incision having any amount of curvature. . . .”<sup>39</sup>

Simply put, Fine is being nitpicky. Fine is technically correct that any incision placed on a curved surface, such as the globe of the eye, which is essentially a sphere, will be a curvilinear form. But, Fine’s departure from Euclidean geometry into the world of Riman geometry is unjustified.<sup>40</sup> It is merely a naked attempt to invalidate Pallin’s patent with any means necessary, even when those means depart from reason and fairness. Although all cataract surgeons know that a straight incision line placed on a curved surface is a curved or curvilinear line when considered in three dimensions, the convention in the field is to refer to incisions from the perspective of Euclidean geometry. It is much like the situation when people refer to the straight line distance between London and Los Angeles on world maps. They know that because the earth is a sphere, the “straight” line between the two cities is a curved line in three dimensions, but they do not refer to the line as curved. They say “straight.” Thus, they are operating from the perspective of Euclidean geometry -- that is, spatial relationships in a two-dimensional, flat world. Likewise, cataract surgeons

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“Small Incision Surgery: Wound Construction and Closure.” Koch describes the frown-shaped incision as having “incision ends sweeping upward away from the limbus” (Fig. 5, p. 663). In the spirit of Fine’s analysis, Koch’s description might be interpreted as describing a straight line incision as well, but Koch clearly does not intend to describe a straight line incision with his words. Of the straight line incision, Koch does write that its “ends are farther away from the limbus than those of the curvilinear incision” (Fig. 3, p. 662). He does not discuss a curvilinear incision with less arc than the limbus.

<sup>39</sup> Fine Declaration, pp. 4-5.





describe incision shapes as if the incisions were made on a “flat world” version of the eye. Thus, a “curvilinear” incision is one that is curved; it could refer to an incision that is parallel to the curvature of the limbus. The “straight line” incision is parallel to a tangent of the limbus when viewed as a two-dimensional projection of the surface of the eye. And, the frown incision is understood to curve away from the tangent to the limbus on the side opposite the cornea. Thus, Fine is overcritical. If his criticisms are taken to be true, then scores of articles, videos, and books in the art would have to be revised because they would not appropriately teach one skilled in the art how to practice a particular technique.

Fine’s only reasonable and uncontroversial point is his observation that Pallin’s patent describes scleral tunnel construction “in only the broadest terms” with no specification of tunnel parameters.<sup>41</sup> Fine correctly concludes that any configuration of tunnel is acceptable under the auspices of the patent.

Fine’s demands on description seem excessive, but his point is well taken that those skilled in the art may be left with uncertainty. While Fine’s inclination toward precision is respectable, it is taken to extremes with Pallin’s patent.

### *Driving the Last Obviousness Nail*

Having had its previous summary judgment motion denied partly because it did not assess secondary considerations of nonobviousness, the defense firmed up its argument for the obviousness of Pallin’s patent.<sup>42</sup> At the core of its obviousness argument was the notion of the innovative and inventive capability of the ordinary person in the field:

“The conclusion as to the obviousness of an invention turns on whether a hypothetical person with ordinary skill and knowledge in the art to which the invention pertains with full knowledge of the pertinent prior art, when faced with the problem to which the claimed invention is

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<sup>40</sup> In Euclidean geometry, lines and shapes exist on a flat, two-dimensional surface, but in Riman geometry, lines and shapes exist on a curved surface. Thus, a line that is considered straight in Euclidean geometry is considered curved in Riman geometry.

<sup>41</sup> Fine Declaration, p. 6.



addressed, would be led naturally to the solution adopted in the claimed invention or at least would naturally view that solution as an available alternative.”<sup>43</sup>

In the assessment of nonobviousness, the hypothetical person is presumed to be aware of all relevant prior art. That hypothetical person would be a surgeon in April 1990 who must address the problem of suture-induced astigmatism – a surgeon who has access to the prior art of Siepser and Gills.<sup>44</sup> However, Pallin would probably characterize the main problem facing the surgeon as one of eliminating sutures.

Ernest raised two points which were central to the defense’s theoretical argument for obviousness (i.e., primary considerations). First, Gills had stated that the difference between the 175 degree incision angle being claimed by Pallin and the 180 degree incision angle inherent to straight line incisions is indistinguishable.<sup>45</sup> He also believed the difference between the two angles is so minuscule that a 175 degree angle for an incision that curves in the direction opposite the curvature of the limbus would be obvious to a person of ordinary skill in the art. He buttresses his assertion with Pallin’s statement to the effect that almost every incision will look like a frown at some point because of stretching and manipulating. Ernest then expresses his belief that the solution to avoiding the “oarlock” effect, a problem which Pallin says the chevron incision solves, is obvious to one of ordinary skill in the art.<sup>46</sup> The solution is simply to move the incision closer to the limbus. The defense delivers a crushing blow to the plaintiff:

“Accordingly, this is not even a case – like almost every obviousness case – where the hypothetical inventor is asked to invent something new. To the contrary, the exact surgical technique used by plaintiff –

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<sup>42</sup> Key elements of the argument were obtained from the written testimony of Ernest who had provided testimony in the second phase of the case.

<sup>43</sup> Quoting p. 49 of Chisum, *Patents*, 1995 in Defendants’ Memorandum Addressing Markman Issues and in Support of Motion for Summary Judgment (filed 2/13/96), p. 49.

<sup>44</sup> Also, Pallin defines the person of average skill as a surgeon who does 200-500 successful cases per year, which the defense agreed with. See 6/13/94 Deposition of Samuel Pallin, p. 60. Cited in Defendants’ Memorandum Addressing Markman Issues and in Support of Motion for Summary Judgment (filed 2/13/96).

<sup>45</sup> Ernest Declaration, pp. 23-4.



and Dr. Gills' successful use of that technique with 375 patients – would be known to the hypothetical inventor. Indeed, even if one assumed for the sake of argument that there was some minute difference in the location of Dr. Gills' incisions and plaintiff's claimed invention (which there was not), plaintiff has never disputed that Dr. Gills' surgical technique produced the same sealing qualities asserted by plaintiff. . . . In other words, the Pallin claims are structurally indistinguishable from Gills' prior art and plaintiff has done no more than assert a minute difference in location that would produce a wholly predictable result [the elimination of "oarlock" effect]. This is not invention."<sup>47</sup>

The defense also stated that adding even the slightest amount of curvature to the inverted V incision, thus producing a frown incision, would be an obvious alternative.

Having been admonished previously for not explaining secondary considerations (e.g. commercial success, long-felt but unsolved needs, and failure of others to invent) as set forth in *Graham v. John Deere Co.*, the defense explained these clearly. In its view, the flurry of activity in sutureless incision development in the spring of 1990 made Pallin's invention obvious:

"In this case, the secondary considerations are entirely consistent with the conclusion that the claimed invention was obvious. In fact, within two weeks of Dr. Siepser's award-winning presentation, both the inverted-V and frown incisions had been designed by surgeons other than plaintiff. By the Fall of 1990 (barely six months later), an entire book on small-incision cataract surgery had been published by Drs.

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<sup>46</sup> Ernest Declaration, p. 29.

<sup>47</sup> Defendants' Memorandum Addressing Markman Issues and in Support of Motion for Summary Judgment (filed 2/13/96), pp. 55-6.



Gills & Sanders, featuring discussions about sutureless surgery techniques by Ernest, Gills, Siepser, McFarland, Kondrot, Bloomberg, Martin and others. And there is no evidence that any of these doctors was even aware of Pallin's work, let alone influenced by it."<sup>48</sup>

(Original emphasis)

The defense noted that the courts have judged an invention obvious when many people using the same prior art arrived at similar solutions.<sup>49</sup> Also, while the plaintiff suggested that he solved a long unmet need, other surgeons had met the need before him. Furthermore, the prior art of other surgeons spread quickly throughout the profession and changed surgical practice. The plaintiff had previously asserted that wide adoption of his incision (commercial success) had shown his invention was nonobvious. However, the defense correctly argued that there is no evidence that the success of sutureless incisions is attributable to Pallin's chevron versus the incisions of other surgeons. The defense distilled its empirical argument for obviousness:

"In short, the sequence of events following the March 1990 ASCRS convention is exactly what one would expect when a claimed invention is simply a natural, and obvious, extension of the prior art."<sup>50</sup>

The defense's prior art argument melded into its obviousness argument. The presence of Gills' work prior to Pallin's first chevron incision constituted a seemingly decisive blow to Pallin's patent because the hypothetical inventor of ordinary skill is privy to all relevant prior art on the day of inventing. The reasoning behind this tenet of the nonobviousness criterion of patentability appears to serve the public well. Even if an inventor like Pallin did not know all of the relevant prior art, the prior art was in the

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<sup>48</sup> Defendants' Memorandum Addressing Markman Issues and in Support of Motion for Summary Judgment (filed 2/13/96), p. 53.

<sup>49</sup> Defendants' Memorandum Addressing Markman Issues and in Support of Motion for Summary Judgment (filed 2/13/96), p. 53, Footnote 65.





public domain. It would only be a matter of time before it would become common knowledge to all in the art. The time required to disseminate this knowledge would likely be much less than the term of a patent. Thus, the public need not grant a patent monopoly on an invention which would be developed anyway as soon as the ordinary surgeon assimilated the relevant prior art.

Throughout much of the case, there was little mention of the ethical issue of patenting medical methods. But the defense's second memorandum for summary judgment contained a short passage, albeit in a footnote, commenting on the issue, perhaps inspired by Robert Portman, one of the new defense attorneys, who has written on the ethical issue in his own right:

“Because plaintiff's patent is clearly anticipated by the prior art and obvious to a person skilled in cataract surgery, it is unnecessary to address the threshold question of the patentability of surgical methods and techniques. Suffice it to say, for the first 150 years of this country's history, both the courts and the Patent Office considered such methods and techniques to be unpatentable. . . . In fact, the issue of whether medical and surgical procedures are patentable is one that has not been squarely addressed by the courts since the Scherer decision.”<sup>51</sup>

Congress addressed it. Would Judge Sessions do so also?

### Acting in Desperation

The plaintiff was becoming desperate. Shortly after the defense filed its second summary judgment memorandum, the plaintiff requested a 60-day extension to reopen the discovery process because

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<sup>50</sup> Defendants' Memorandum Addressing Markman Issues and in Support of Motion for Summary Judgment (filed 2/13/96), p. 54.

<sup>51</sup> In the Scherer decision, the Patent Office Board of Appeals decided that patenting a method which treats the human body but has as its object some medical or surgical purpose is patentable. This 1954 decision cleared the path for the patenting of medical methods. Defendants' Memorandum Addressing Markman Issues and in Support of Motion for Summary Judgment (filed 2/13/96), p. 37, Footnote 51. Also, refer to section on medical procedure patents in “Patents: a subset of intellectual property instruments” chapter.



the defense had submitted new evidence, including Gills' revised testimony, the declaration of Gills' surgical assistant, William Ausmus, and the postoperative photograph of Patient 201820. The plaintiff said that it had not been informed of the new evidence during the period in which legal briefs were being written. The plaintiff wanted to depose Gills and Ausmus in order to prepare a rebuttal. Alternatively, the plaintiff stated it would rescind its request if the newly submitted evidence was excluded.

It was legitimate for the plaintiff to express a desire to examine new evidence. However, requesting an extension of 60 days for one or two depositions was excessive but perhaps not an unexpected tactic in light of the crushing blows the defense had delivered.<sup>52</sup>

The defense styled the extension request as an attempt to avoid and delay.<sup>53</sup> The defense declared that Gills merely elaborated on his previous testimony, and it was therefore unnecessary to question him again. The defense pointed out that Pallin's previously submitted testimony "departed radically" from his declaration in court documents.<sup>54</sup> The defense preempted further tactics to extend and delay by offering to exclude Gills' statement that he measured incision distances in connection with clinical studies, and to fly Ausmus to Washington, DC for deposition by plaintiff's counsel. Such an offer would seem to imply the defense was confident in its legal position and desired a rapid resolution.

After receiving the offer, the plaintiff expressed anger over its inability to depose Gills properly. Concerned that Gills was emerging as the central witness in the case, the plaintiff angrily complained that Gills had only made himself available for two-hour slots starting at 7pm on weekdays during the deposition period.<sup>55</sup> The plaintiff had no interest in deposing Gills in twenty two-hour sessions. Frustration over deposing Gills had been brewing since 1994 as shown in the following excerpt from a May 1994 letter from Longacre to Neuner:

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<sup>52</sup> The plaintiff had also filed opposition to the *Markman* hearing, perhaps to avoid being blown out in the hearing. See "Markman" chapter.

<sup>53</sup> Outrage permeated its opposition memo: "It is equally hard to understand how plaintiff can urge that the schedules of some of the busiest surgeons in the country be rearranged again, simply to accommodate the vacation schedule of one of plaintiff's four attorneys – even though plaintiff has known for months that briefing and the *Markman* hearing would proceed in March!" (Opposition of Dr. Singer and the Hitchcock Clinic to Plaintiff's Motion to Extend the Schedule and Reopen Discovery (filed 2/23/96), p. 9.).

<sup>54</sup> Opposition of Dr. Singer and the Hitchcock Clinic to Plaintiff's Motion to Extend the Schedule and Reopen Discovery (filed 2/23/96), p. 7, Footnote 7.



“You also told us this was the only date that he could be available.

That was untrue as you have indicated other days. It is likewise untrue that Dr. Gills cannot be available except at 7 PM on selected nights.

He just does not want to be available. . . .Further, how can you be so sure that we need only two hours or so? Have you checked in our notebook? Do you know what questions we have? Do you know how they will be answered? Why do you think that Dr. Gills will take less time than Dr. McKool who had no documents and has written very little. // Finally, when we arranged the Pallin deposition you originally insisted that the depositions be during the week during normal business hours. We argued for Saturday and Sunday. Finally you agreed to Saturday but drew the absolute line at Sunday. Now 7 PM is reasonable? // We are entitled to have Dr. Gills fresh and for a long enough continuous period so we have continuity.”<sup>56</sup>

But most troubling was Gills’ apparent unwillingness to accommodate the plaintiff:

“Clearly the scheduling of Dr. Gills’ deposition in this case has been a BIG problem and had defied ordinary efforts to resolve. Other doctors in this case who are equally busy, including Drs. Pallin and Ernest have made themselves available on Saturdays for 4 hour plus depositions. Moreover Dr. Gills has now volunteered his services as a declarant. If his view were that he was too busy to participate in this case that would

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<sup>55</sup> Reply to Defendants’ Opposition to Plaintiff’s Motion to Extend Time for Response and Reopen Discovery or in the Alternative to Exclude Evidence of Dr. Gills & William H. Ausmus (filed 2/28/96), p. 1.



be one thing, but it seems he is too busy except to participate on Defendants' side. . . .Equally clear is that sixty days to schedule a deposition is a reasonable figure when it comes to Dr. Gills."<sup>57</sup>

While requesting the opportunity to examine the new evidence seemed reasonable, the plaintiff's other requests and complaints were excessive. The plaintiff had requested that Gills' facility, staff, and equipment be available for discovery instead of flying Ausmus to counsel's office Washington, DC. While making Gills' facility, staff, and equipment available would help the plaintiff, it is not clear why this would be necessary. This excessive request combined with another mention of its opposition to holding a *Markman* hearing signified moves of desperation.<sup>58</sup>

Consistent with a state of desperation in his lawsuit, Pallin informed White in a letter dated February 27, 1996 that he had sustained a shoulder injury while horseback riding that might preclude his presence at the *Markman* hearing in March:

"Please be advised that on Monday, February 19, 1996 I was injured falling from a horse and sustained a wide separation of the acromioclavicular junction of the left shoulder and lacerations to the head and ear. I have been enduring significant pain and disability from my injuries and it is unlikely that I will be able to travel cross country in March. I am under the care of an orthopaedic surgeon, and x-rays and physician's notes are available if confirmation of my injuries is

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<sup>56</sup> 5/3/94 Letter from Longacre to Neuner as Exhibit O in Reply to Defendants' Opposition to Plaintiff's Motion to Extend Time for Response and Reopen Discovery or in the Alternative to Exclude Evidence of Dr. Gills & William H. Ausmus (filed 2/28/96).

<sup>57</sup> Reply to Defendants' Opposition to Plaintiff's Motion to Extend Time for Response and Reopen Discovery or in the Alternative to Exclude Evidence of Dr. Gills & William H. Ausmus (filed 2/28/96), pp. 4-5.

<sup>58</sup> Regarding *Markman*, the plaintiff now agreed that scope of claims is a common point of analysis for infringement and patent validity but stated that further fact-finding was necessary for the issue of patent validity. Reply to Defendants' Opposition to Plaintiff's Motion to Extend Time for Response and Reopen Discovery or in the Alternative to Exclude Evidence of Dr. Gills & William H. Ausmus (filed 2/28/96), p. 8.





desired. Coincidentally, I also injured my left knee two weeks earlier and have been scheduled for elective knee surgery to correct a medial meniscus tear. This surgery will take place on Monday, March 4, 1996 and was actually planned before the above-referenced accident. It is still unclear whether or not surgical treatment will be required for the shoulder injury.

I would like to respectfully submit that a later date for the hearing would be more appropriate in view of my circumstance. I feel it is imperative that I be present during the hearing. The defendants have expended considerable monies and manpower and have extensive resources but we have only my own testimony to represent our case. It would be grossly unfair to force me to be present in my injured condition or to proceed in my absence.”<sup>59</sup>

The content of the letter may have been true, but given the situation for the plaintiff in which he had been forced to retreat by narrowing his claims, one could reasonably believe this was a delaying tactic.

#### Hinging the Case on Patent Invalid or Patent Not Invalid

On March 21, 1996, the plaintiff filed opposition to the defendants’ motion for summary judgment and then filed a Cross Request for Judgment of Patent Not Invalid.<sup>60</sup> Thus, both sides had essentially filed for summary judgment. The fate of the case was now completely in the hands of Judge Sessions. If the judge ruled favorably on the defense’s motion, there would be no trial. The case would be over as Pallin’s patent would be found invalid. If the judge ruled adversely on the defense’s motion, the case would go to trial. Pallin would have the opportunity to present his case to a jury which would resolve

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<sup>59</sup> 2/27/96 Letter from Pallin to White. Copy filed with U.S. District Court of Vermont on 2/29/96.

<sup>60</sup> Plaintiff’s Memo in Opposition to Defendants’ Motion for Summary Judgment of Invalidity and Cross Request for Judgment of Patent Not Invalid (filed 3/21/96).



“the complex factual disputes” that Judge Billings had referred to in his Opinion. If Judge Sessions ruled favorably on the plaintiff’s motion, the case would shift back to an infringement case. Pallin’s patent would have been found valid, implying that the alleged prior art presented by the defense would not anticipate his invention. If the judge ruled adversely on the plaintiff’s motion, then the patent would have been found invalid.<sup>61</sup> By the nature of the motions filed by the opposing parties, the judge would have to favor either the plaintiff or the defendants. He could not rule favorably for both or adversely for both because the case hinged on one issue with only two outcomes: either the patent is invalid or not invalid. What began as an effort to prove that Singer and the Hitchcock Associates of Randolph infringed Pallin’s patent had been transformed into a trial on the validity of the patent.

At this stage of the case, the defense sought to invalidate the patent, and the plaintiff tried to move to trial with his patent intact. Of note, Pallin launched a broadside attack on Gills’ credibility and on his inverted V incision. The essence of the plaintiff’s argument lie in showing that Pallin lawfully represented his knowledge at the PTO, the evidence offered by Gills was not trustworthy, the evidence presented by the defense did not constitute prior art, and Pallin’s invention was nonobvious by primary<sup>62</sup> and secondary considerations (See Core Arguments C).

### *Taking Another Look at Credibility*

In attempting to clear himself from the charge of inequitable conduct at the PTO, Pallin wrote that at the time of his invention in April 1990, “the alleged prior work of Dr. Gills with respect to his inverted V incision was unknown to me and was to my knowledge unpublished in ophthalmology.”<sup>63</sup> Regarding the question of why Pallin did not disclose the work of Siepser and McFarland to the PTO, the plaintiff stated

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<sup>61</sup> If for some reason, the judge decided to invalidate only the four patent claims at issue, then this would weaken but not nullify the patent. Two of the patent’s four independent claims and two of the remaining 25 dependent claims would be invalid. The claims that Pallin enforced were aimed toward Singer’s patent, so general claims and claims pertaining to a curvilinear incision would be invalidated.

<sup>62</sup> In support of the nonobviousness of Pallin’s invention, the plaintiff drew from the testimony of the defense’s expert witnesses. The plaintiff remarked that Fine did not believe sutureless surgery was feasible yet now said that it was obvious. The plaintiff also noted that Ernest had characterized the person of ordinary skill as someone who knew nothing about eliminating sutures. See Plaintiff’s Memo in Opposition to Defendants’ Motion for Summary Judgment of Invalidity and Cross Request for Judgment of Patent Not Invalid (filed 3/21/96), p. 2-4.

<sup>63</sup> Pallin Declaration (3/21/96), pp. 16-17.



that the defense did not assert that the work of these other surgeons anticipated Pallin's invention; thus, this work does not have bearing on the Pallin patent. This is a reasonable argument, but the plaintiff fails to acknowledge that the defense had stated that if straight line incisions are covered by the patent, then McFarland's work anticipates Pallin's work. Also, the defense may not have asserted Siepser's work as anticipating because it could assert the same more convincingly with the incisions of others.<sup>64</sup>

Most damaging for the defense was the plaintiff's argument that the testimonial and photographic evidence presented by Gills and his staff was not reliable. The plaintiff portrayed Gills and his surgical assistant, Sherri Gillis, as revisionist witnesses. The plaintiff remarked that none of the "critical" elements (3-4 mm incision distance, corneal valve, perfect scleral flap) in Gills' 1990 book were evidenced in his March 1990 operative notes.<sup>65</sup> Gills now said external incision dimensions do not matter for self-sealing. In the plaintiff's view, Gills' report that he had performed 350+ sutureless surgeries before Pallin's first chevron incision was hearsay because Gills had only been able to furnish one photo as proof of his work. Earlier in the case, Gills had submitted a photo which did not match the photo in his book as he had claimed. Gills committed a similar but more serious mistake this time by submitting records of sutureless surgeries in which sutures were used.<sup>66</sup> Finally, Sherri Gillis had initially said the inverted V incision groove was 3 millimeters from the limbus but later revised it to 2.0-4.0 millimeters.

Also troublesome for Gills were the clear contradictions between his testimony and that of his staff.<sup>67</sup> Although Gills stated that he performed the inverted V incision, Gillis testified that she often made the incision and the scleral groove tunnel. Gillis testified that angles of 90-120 degrees were used for the inverted V but Gills recalled ranges of 70-150. Regarding measurement, the plaintiff wrote:

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<sup>64</sup> One might ask what bearing Kondrot's work, which was cited by Pallin in his August 1990 Letter to the Editor of the *Journal of Cataract and Refractive Surgery*, has on Pallin's invention, as it was reported in March 1990.

<sup>65</sup> Plaintiff's Memo in Opposition to Defendants' Motion for Summary Judgment of Invalidity and Cross Request for Judgment of Patent Not Invalid (filed 3/21/96), p. 26.

<sup>66</sup> The plaintiff wrote: "Hence, on this occasion of delving into Dr. Gills operative notes, exclusively for the purpose of this lawsuit and this declaration to rid the world of the Pallin patent, Dr. Gills notes reveal sutures used in what he says is "operative notes of several sutureless surgeries." Well, which is it? Is it sutureless or not? Dr. Gills declaration and the offered notes do not match up. Again!" Plaintiff's Memo in Opposition to Defendants' Motion for Summary Judgment of Invalidity and Cross Request for Judgment of Patent Not Invalid (filed 3/21/96), pp. 23-4.

<sup>67</sup> Plaintiff's Memo in Opposition to Defendants' Motion for Summary Judgment of Invalidity and Cross Request for Judgment of Patent Not Invalid (filed 3/21/96), pp. 25-6.



“Finally, Sherri Gillis does not recall ever measuring one of these incisions and, if she did, it was “very rarely” done. Dr. Gills managed to measure several in this time period (March-April 1990) for use in controlled studies he was apparently doing which were unknown to Ms. Gillis who never witnessed any measuring. . . Of course, no records were kept of these studies, nor are any notes for these studies available, and this rare event of measuring managed to escape Sherri Gillis’ attention altogether.”<sup>68</sup>

The plaintiff sarcastically questioned if Gills and Gillis were even present in the same room, performing the same procedures, or even observing the same events, and then added that this evidence was neither clear nor convincing.

To make matters worse for the defense, the plaintiff charged fraudulent photographic evidence as it continued to chip away at Gills’ credibility. In the plaintiff’s view, Gills was creating “prior art circa April 1990” by photographing a patient in 1996. Citing rules of evidence which require photos to be authenticated, the plaintiff concluded: “this self-serving photograph was specifically created for this litigation.”<sup>69</sup> The plaintiff correctly pointed out the poor quality and ambiguous nature of the photograph.<sup>70</sup> The photo shows a portion of the limbus and a barely visible (due to photographic quality) inverted V scar on a portion of the sclera. What is presumably a millimeter scale is adjacent to the incision and the limbus, but the scale possesses no calibration markings. If it is indeed a millimeter scale, then the apex of the incision lies between 2 and 3 millimeters posterior to the limbus, which is within the range specified by Pallin. The photograph contains handwritten text: “208120” below the image, “Surg. Date 3-19-90” on

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<sup>68</sup> Gillis Dep. Defendants’ Exhibit N, pp. 11-12. Plaintiff’s Memo in Opposition to Defendants’ Motion for Summary Judgment of Invalidity and Cross Request for Judgment of Patent Not Invalid (filed 3/21/96), p. 25.

<sup>69</sup> Plaintiff’s Brief in Support of Pretrial Motion in Limine to Suppress Photograph and Declaration as Evidence (filed 3/21/96), p. 5. Cites Rule 901(a) of Federal Rules of Evidence.

<sup>70</sup> See Exhibit 1 and p. 3 in Plaintiff’s Brief in Support of Pretrial Motion in Limine to Suppress Photograph and Declaration as Evidence (filed 3/21/96).





top, and “2.6.96” in the bottom right-hand corner. The plaintiff noted that the handwriting is anonymous and the photo possesses no distinguishing marks, such as a date/time stamp, made during the diagnosis or treatment process. Viewing the photo as an out of court hearsay statement that is not submitted under oath, the plaintiff wrote:

“Although the Defendants claim to have utilized this highly experimental process at a time when it was novel and even ridiculed by many in the profession, they did not document the groundbreaking procedure at the supposed time of the surgery in 1990. Instead, they only photographed the alleged patient who received the experimental procedure years later when litigation for use of the Pallin method was already into its fourth year. . .”<sup>71</sup>

To add insult to injury, William Ausmus, Gills’ surgical assistant who was claimed to have photographed Patient 208120, did not photograph the patient, did not observe the process of taking the photograph, and could not identify who had written the text on the photograph. Ausmus had, however, examined the patient twice over a period of many years, although he could not recall when he last saw the patient.<sup>72</sup>

Ausmus had also stated in deposition that two-week postop scars can look like multiple-year postop scars.<sup>73</sup> The plaintiff noted that if one cannot distinguish a two-week-old scar and a six-year-old scar, then it is possible to submit a photograph of a two-week-old scar and claim it is much older.

The plaintiff filed a motion to exclude the photograph of Patient 208120 and the declaration of Ausmus as evidence. While the strategy was clearly to challenge the credibility of the photographic evidence and witness testimony, the plaintiff had good reason to offer a challenge. The photograph of

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<sup>71</sup> Plaintiff’s Brief in Support of Pretrial Motion in Limine to Suppress Photograph and Declaration as Evidence (filed 3/21/96), p. 7.

<sup>72</sup> Ausmus Declaration, p. 13.

<sup>73</sup> 3/14/96 Ausmus deposition, pp. 22-23.



Patient 208120 could not be authenticated, and it emerged under suspicious circumstances.<sup>74</sup> Without authentication, the defense would have a harder time proving that Gills' inverted V predated Pallin's chevron. The plaintiff added that Ausmus' testimony was self-serving and prejudicial.

The plaintiff had managed to legitimately question the credibility of the photo, but Ausmus facilitated the erosion of his own credibility. Ausmus stated in deposition that Gills had used a sutureless incision on Patient 208120 on March 19, 1990, but Ausmus was not present in the operating room. Given that Gills often has his surgical assistants, such as Ausmus and Gillis, make the initial incisions, the plaintiff cast doubt on Ausmus' statement.<sup>75</sup> Ausmus testified that the photo constituted a "fair and accurate depiction" of the patient's eye, but Ausmus was not present when the photo was taken. Also, Ausmus did not appear forthcoming in his deposition. Twice he was asked when it was that he took the photo of the patient. Twice he replied that he did not know. Only some time later did he admit that he did not take the picture.<sup>76</sup> Finally, Ausmus admitted that defense counsel wrote his declaration for him.

Four days later, the defense shot back portraying the plaintiff's effort to suppress the photograph of Patient 208120 and Ausmus' testimony as a "desperate attempt" to exclude definitive evidence of the inverted V incision used within three millimeters of the limbus. Citing surgical notes, the defense reasserted that Gills had used the inverted V on April 19, 1990 and emphasized that Ausmus had personally measured the incision-limbus distance on the left eye of Patient 208120 on February 6, 1996.<sup>77</sup> In the defense's view, "[t]he fact that Mr. Ausmus did not take the photo himself and was not present when it was taken is immaterial, particularly where the photo was taken by a fellow employee shortly after Mr. Ausmus examined the patient's eye." Mark Erickson, a certified retinal angiographer and ophthalmic technician, testified that he had used a photo slit lamp biomicroscope on February 6, 1996 to photograph

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<sup>74</sup> Plaintiff's Brief in Support of Pretrial Motion in Limine to Suppress Photograph and Declaration as Evidence (filed 3/21/96), p. 4.

<sup>75</sup> Although the names of primary surgeons and their assistants (and medical students or other staff) are listed in an operative report, the individual identity of the surgeon, assistant, or student that performed a particular component of the surgical procedure is often not listed. Thus, a medical student may perform all components of an appendectomy procedure, but the operative report may only list the steps of the appendectomy and state that the medical student was present.

<sup>76</sup> Ausmus deposition, p. 13, 20.

<sup>77</sup> Defendants' Opposition to Plaintiff's Pretrial Motion in Limine to Suppress Photograph and Declaration as Evidence (filed 3/25/96), pp. 1-2, 4.



the left eye of Patient 208120.<sup>78</sup> He took the picture for the purpose of measuring incision-limbus distance. He also testified that he had written the patient number and the date the picture was taken on the bottom edge of the photograph. Regarding the plaintiff's assertion that the photo constituted hearsay and therefore should be excluded, the defense wrote:

“Practically speaking, the photograph of patient 208120's is no more an out of court statement than a picture of the scene of an automobile accident.”<sup>79</sup>

Having authenticated the photograph with reasonable arguments, the defense thrust the case back to the main issues of infringement and anticipation.

#### *Solving the Inconsistency Over Suture Use*

The plaintiff reiterated its view that the essence of Pallin's invention as set forth in the patent preamble (abstract) is that of a sutureless incision.<sup>80</sup> The plaintiff seemed confounded by the defense's view:

“Of course, according to the defendants, if the term [“substantially self-sealing”] has any meaning at all, it means that the claimed method can include a stitch. . . .Is the Patent Office so incompetent as to issue a patent covering exactly what the very document itself characterizes as being a part of the prior art?”<sup>81</sup>

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<sup>78</sup> Declaration of Mark Erickson, p. 1-2.

<sup>79</sup> Defendants' Opposition to Plaintiff's Pretrial Motion in Limine to Suppress Photograph and Declaration as Evidence (filed 3/25/96), p. 8.

<sup>80</sup> Pallin flatly stated that incisions which do not self-seal and require a suture are not covered by his patent. Plaintiff's Memo in Opposition to Defendants' Motion for Summary Judgment of Invalidity and Cross Request for Judgment of Patent Not Invalid (filed 3/21/96), p. 13.



The source of the debate over the use of a suture in the chevron incision lies in differing views on patent interpretation. In the interpretation of patents, the patent claims set forth the scope of the invention, and the patent description (non-claim text or specifications) limits the scope of the claims. In the defense's view, the preamble (abstract) does not limit the scope of the claims because it is external to the body of the patent. Therefore, the text in the patent about occasionally using a suture for larger incisions is not neutralized by text which sets forth the essence of the invention. However, the plaintiff sees the preamble (abstract) as internal to the patent that lends description to the patent claims. In this view, the essence of the invention – an incision that does not require sutures for sealing – constitutes a pervasive theme of the patent. However, if the preamble text limits the claims, then the description text about using a suture must also limit the claims. This leads to a contradiction. But the Supreme Court has ruled that if there are two constructions of a patent, the construction which secures the invention to the patentholder should be adopted and not the construction which is fatal to the patent.<sup>82</sup>

*Attempting to Distance the Chevron from Alleged Prior Art*<sup>83</sup>

- Trumpeting the virtues of his incision

In an effort to distinguish his incision method from those of others, the plaintiff reiterated that Pallin sought a sutureless water-tight incision that could admit both soft and hard IOLs and could be reproduced by the ordinary person in the art.<sup>84</sup> Pallin found unacceptable the techniques of Siepser, McFarland, Ernest, and Gills because they all “exclusively” required using a foldable IOL which was

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<sup>81</sup> Plaintiff's Memo in Opposition to Defendants' Motion for Summary Judgment of Invalidity and Cross Request for Judgment of Patent Not Invalid (filed 3/21/96), pp. 16-17.

<sup>82</sup> Plaintiff's Memo in Opposition to Defendants' Motion for Summary Judgment of Invalidity and Cross Request for Judgment of Patent Not Invalid (filed 3/21/96), pp. 31-32.

<sup>83</sup> The only prior art counterarguments leveled by the plaintiff were against Ernest and Singer. The plaintiff still questioned if what Ernest claimed he presented at grand rounds at Wayne State University was published. In distinguishing Pallin's incision, the plaintiff noted that sutureless surgery was not one of Singer's aims or accomplishments in developing his incision. Plaintiff's Memo in Opposition to Defendants' Motion for Summary Judgment of Invalidity and Cross Request for Judgment of Patent Not Invalid (filed 3/21/96), p. 22, 47 respectively.

<sup>84</sup> Plaintiff's Memo in Opposition to Defendants' Motion for Summary Judgment of Invalidity and Cross Request for Judgment of Patent Not Invalid (filed 3/21/96), p. 10.





compressible to 3.5 millimeters.<sup>85</sup> Pallin noted that Siepser's radial incision would require extending the incision superiorly to admit other types and sizes of lenses; this could result in anatomical disruption of the equatorial region of the eye.<sup>86</sup> Pallin saw "unacceptable oarlock effect" and possible damage to the ciliary body with McFarland's technique.<sup>87</sup> Pallin believed these "techniques were virtually non-transferable to the surgeon of average skill in the art at that time."<sup>88</sup>

- Responding to Dr. Howard Fine

Pallin then clarified a number of issues, many of them stemming from Howard Fine's criticisms. In response to Fine's charge that the Pallin patent did not teach a person in the art how to make and use the invention, Pallin stated that he had spent much time to make sure his patent enabled the practitioner in the art.<sup>89</sup> Perhaps in response to Fine's comments, Pallin modified his description of the shape of his incision which he now said was an incision that "diverges from the limbus from a central location and looks like a chevron."<sup>90</sup> He added a more detailed description of incision and tunnel structure:

"As the frown or chevron style scleral incision diverges from the limbus along the surface of the globe, the result is a three dimensional curving and expanding funnel structure, from the scleral groove to the eye entrance, having continuously varying dimension, geometry, and sealing character throughout its shape."<sup>91</sup>

Regarding comments made by defense witnesses that the limbus was an approximation, Pallin reiterated that his patent defined limbus as the border between the clear cornea and white sclera. He added: "The

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<sup>85</sup> Declaration of Samuel Pallin, M.D. in Support of Plaintiff's Opposition to Defendants' Motion for Summary Judgment (filed 3/21/96), p. 15.

<sup>86</sup> Declaration of Samuel Pallin, M.D. in Support of Plaintiff's Opposition to Defendants' Motion for Summary Judgment (filed 3/21/96), pp. 8-9.

<sup>87</sup> Pallin believed that stretching the incision to insert a lens implant could lead to unroofing of the ciliary body.

<sup>88</sup> Pallin Declaration (3/21/96), pp. 8-9.

<sup>89</sup> Pallin Declaration (3/21/96), p. 14.

<sup>90</sup> Pallin Declaration (3/21/96), p. 10.



limbus is an anatomical landmark understood by all surgeons skilled in the art since the beginning of modern cataract surgery.”<sup>92</sup> Thus, it would appear that there was a fundamental difference in the way Pallin and two of his peers viewed the nature of the limbus for the purposes of measuring incision distances. Finally, Pallin reiterated that his patent did not cover straight lines.<sup>93</sup> He noted that the language, such as “extend laterally away from” and “curvilinear configuration,” in the patent spoke against straight lines. He also noted that his patent discusses straight lines as being part of prior art. Pallin writes, “a “straight line” cannot be created on the surface of a sphere. Hence it is inconsistent to conclude that my patent may cover a straight line.”<sup>94</sup> Interestingly, Fine expressed the same concept of a “straight” line being curvilinear on a curved surface. While Fine uses this concept to say that Pallin’s patent then covers all incisions, Pallin uses this concept to simply say that his patent does not cover straight lines, thus attempting to escape the prior art of McFarland and Ernest. However, if a “straight” line cannot be placed on a sphere, then McFarland’s and Ernest’s “straight line” incisions are likewise curved lines. Thus, Pallin could not really escape the prior art of these incisions.<sup>95</sup>

- Taking Aim at the Prior Art of Gills

The plaintiff then enhanced its case that Gills had failed to conceive of his sutureless incision because he did not have a permanent idea of the invention. In its view, a “rational jury” would conclude the same after assessing Gills’ credibility.<sup>96</sup> If it could be proven that Gills’ did not conceive, then his work would be discarded as anticipating prior art. In Pallin’s view, at the time of the first chevron, Gills’ inverted V incision was experimental at best and therefore could contribute little to the knowledge accessible to a person of ordinary skill in the art.<sup>97</sup> According to Pallin, other shortcomings of Gills’ work

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<sup>91</sup> Pallin Declaration (3/21/96), p. 12.

<sup>92</sup> Pallin Declaration (3/21/96), p. 12.

<sup>93</sup> Plaintiff’s Memo in Opposition to Defendants’ Motion for Summary Judgment of Invalidity and Cross Request for Judgment of Patent Not Invalid (filed 3/21/96), p. 27.

<sup>94</sup> Cites col. 1, lines 56-59. Pallin Declaration (3/21/96), p. 32.

<sup>95</sup> The memo states that Pallin’s patent “plainly discloses appropriate tunnel widths and lengths” but offers no numerical values. Plaintiff’s Memo in Opposition to Defendants’ Motion for Summary Judgment of Invalidity and Cross Request for Judgment of Patent Not Invalid (filed 3/21/96), p. 19.

<sup>96</sup> Plaintiff’s Memo in Opposition to Defendants’ Motion for Summary Judgment of Invalidity and Cross Request for Judgment of Patent Not Invalid (filed 3/21/96), p. 45, 46.

<sup>97</sup> Pallin Declaration (3/21/96), p. 17.



included that Gills had “estimated, guesstimated” incision distances,<sup>98</sup> changed his views on where the incision should be placed relative to the limbus,<sup>99</sup> required incision elements for self-sealing which Pallin did not need for the chevron incision,<sup>100</sup> and did not contemplate the use of hard IOLs with the sutureless incision.<sup>101</sup> Pallin concluded that Gills did not know what he was doing. Pallin believes Gills abandoned the inverted V because he saw no benefit in it.<sup>102</sup>

The plaintiff noted that Gills failed to keep notes of his procedures or wrote only poorly detailed notes. This behavior was contrasted with that of Pallin, Ernest, and Singer, whom the plaintiff asserted kept detailed surgical notes.<sup>103</sup> Many of Gills’ operative notes only contained references to a “scleral groove incision” without specific description of incision size and angle. Gills’ work was only being revealed in 1996:

“At long last in 1996, Mr. Ausmus allegedly measures the location  
used by Dr. Gills six years ago, and defendants conclude this was in the

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<sup>98</sup> See Gills deposition, Exhibit M, page 9, lines 16 to end, page 10 to lines 5 and page 18, line 22; cited in Pallin Declaration (3/21/96), p. 17.

<sup>99</sup> Pallin notes that when Gills first contributed to the case, he stated that the incision apex could be placed 1.5-3.5 to 4 millimeters from the limbus and that where the apex is placed did not make any difference. However, Gills first published book stated it was “critical” to place the apex of the inverted V incision at least 3-4 millimeters from the limbus. Pallin points out that Gills’ book was at odds with his 1994 testimony, in which, Pallin points out, Gills does not even speculate how the incision might work in a range 1.5-3.0 mm from the limbus. (Page 128, lines 7-8, and line 24 of Chapter 8, Gills book, Exhibit 12; cited in Pallin Declaration (3/21/96), p. 17.) According to Pallin, Gills book teaches away from his patent because it advocates a range of 3.0-4.0 mm, which is outside the patent (barring the overlap of 3.0 mm, technically speaking). Finally, Pallin states that Gills’ 1991 book shows that it was the first time Gills had used calipers to measure incision distances. (Pallin Declaration (3/21/96), pp. 19-20.) According to Pallin, Gills’ 1991 book rejects Gills’ previous hypothesis that 3-4mm is critical and finds Pallin’s range to be correct.

<sup>100</sup> Pallin distinguishes his incision by saying that it does not require “perfect scleral flaps” or a corneal valve, which Gills believes is necessary for self-sealing of the inverted V incision.<sup>100</sup> Pallin also recounts Gills writing in his 1996 declaration that the necessity of “perfect scleral flaps” written about in his book constituted a misunderstanding. Pallin stated that such a misunderstanding, even if it occurred after the first chevron, still reveals something about what happened before the first chevron. Nevertheless, “perfect scleral flaps” are common in cataract surgery.

<sup>101</sup> All inverted V incisions use foldable, 3.5 mm lenses. And, Gills uses a straight 6 or 6.5 mm incision for inserting hard IOLs. Pallin cites Gills book, Exhibit 12, page 128, lines 5-6; Pallin Declaration (3/21/96), pp. 20, 29.

<sup>102</sup> Pallin Declaration (3/21/96), p. 17.

<sup>103</sup> Plaintiff’s Memo in Opposition to Defendants’ Motion for Summary Judgment of Invalidity and Cross Request for Judgment of Patent Not Invalid (filed 3/21/96), pp. 26-7.



“prior art all along” although unarguably it was unknown to anyone, even Dr. Gills, until 1996.”<sup>104</sup>

In a final effort to distinguish his incision, Pallin comments on the significance of scale in cataract surgery:

“All cataract surgery is micro-surgery conducted while observing through a microscope. All movements are on the order of millimeters and fractions of millimeters. Such millimeter distances can and do have a profound effect on the surgery. This view that millimeters matter a great deal is bolstered by the views of Drs. Ernest and Singer who place great emphasis on a 0.5 - 1.5 mm corneal flap or valve being the entire basis or self-sealing. (With which I disagree as a basis of self-sealing). Small dimensions of a mm or less make a BIG difference in cataract surgery. All surgeons in this field should agree on that principle. For example - instrument trapping occurs in tunnel lengths >3mm - but does not occur in lengths <3mm.”<sup>105</sup>

The plaintiff described the chevron incision as novel because no other incision technique offered the same combination of features. It accused the defense of lumping all prior art together in an effort to invalidate Pallin’s patent. Finally, the plaintiff expressed its belief that the defense was motivated by general opposition to medical method patents, implying that the Pallin patent was being unfairly victimized. In light of this and other arguments, the plaintiff concluded that the defense had not met the burden of proof for patent invalidity.

#### *Refuting charges of obviousness*

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<sup>104</sup> Pallin Declaration (3/21/96), p. 29.





The plaintiff combated assertions of obviousness by asserting that other surgeons had failed to conceive of or to sustain his incision method<sup>106</sup> The plaintiff argued that Gills had failed in his pursuit of a sutureless incision; he had tried for five years to achieve suturelessness with the use of metabolic agents but failed. The plaintiff also stated that Gills had abandoned his incision after he arrived at the conclusion that the shape of the incision makes no difference in sealing. This is an exaggeration because Gills used his incision less often and did not completely abandon it. The plaintiff also stated that the McFarland method did not last in the cataract surgery field. Finally, the plaintiff asserted that neither Gills nor Singer appreciated what they were working with in terms of self-sealing.

### Mounting the Final Defense

The defense did not respond to every argument in the plaintiff's opposition memo but instead focused on rebutting key points and crystallizing its most powerful arguments for patent invalidity. The defense agreed with Pallin's definition of the limbus as the transition zone between cornea and sclera, but it pointed out that different surgeons measure from different points on the limbus, implying that the incision distance range specified in the patent would only be an approximation.<sup>107</sup> The defense believed that it was unnecessary to resolve the straight line issue because the work of Gills and Singer invalidated the Pallin patent. It acknowledged that Pallin reversed his position on this issue in order to avoid the prior art of Ernest.<sup>108</sup> Regarding the suture use issue, the defense pointed out that in spite of the fact the plaintiff claimed that sutures are forbidden by the abstract of the patent, Pallin had said, in deposition, that a suture may be required for larger incisions.<sup>109</sup> The defense correctly stated that the plaintiff did not address the issue of the patent text which teaches the use of a suture. Pallin speaks of a sutureless and watertight

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<sup>105</sup> Pallin Declaration (3/21/96), p. 21.

<sup>106</sup> See Plaintiff's Memo in Opposition to Defendants' Motion for Summary Judgment of Invalidity and Cross Request for Judgment of Patent Not Invalid (filed 3/21/96), pp. 20, 69; and Pallin Declaration, p. 29.

<sup>107</sup> Dr. Singer and Hitchcock Clinic's Reply Memorandum in Support of Motion for Summary Judgment (memo not date/time stamped), p. 4.

<sup>108</sup> The defense notes that Pallin had said, in deposition on 1/8/94 and 6/13/94) that his patent covered straight lines. See Dr. Singer and Hitchcock Clinic's Reply Memorandum in Support of Motion for Summary Judgment (memo not date/time stamped), p. 4.

<sup>109</sup> Dr. Singer and Hitchcock Clinic's Reply Memorandum in Support of Motion for Summary Judgment (memo not date/time stamped), p. 5, 7.



incision as the result of his method but then does not acknowledge the fact that this may not always result with larger incisions. The defense distilled the argument to the following:

“The problem here is that plaintiff insists on the one definition (watertight and sutureless) that would render the word “substantially” meaningless. And he insists on this now, even though this contradicts his sworn testimony and the clear instruction of the patent when a six millimeter lens is being used.”<sup>110</sup>

The defense stated that the plaintiff could have chosen narrower terms for his patent but instead chose “very broad language in order to maximize the reach of his patent and the potential for gaining royalties. He cannot rewrite its language here, in a futile attempt to escape prior art that anticipated his claimed invention.”<sup>111</sup> Finally, the defense dismissed the plaintiff’s argument that only prior art which might anticipate must be disclosed at the PTO. The defense stated that Pallin did not fulfill his duty of disclosing any prior art, whether it anticipates or not, that may be material to the PTO in patent examination.<sup>112</sup>

#### *Anticipation defense*

The defense stated simply that Singer and Gills had used the same incision distance and geometry as Pallin had.<sup>113</sup> Singer used a single suture for a 6 millimeter lens as permitted in the Pallin patent, and the plaintiff had not been able to show that Singer had not achieved the same results. The defense combated the charge of “estimated, guesstimated” by saying that Pallin himself estimates and that the margin of error in measuring is 0.5 millimeters, implying that Gills did place incisions within the range specified in the Pallin patent.

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<sup>110</sup> Dr. Singer and Hitchcock Clinic’s Reply Memorandum in Support of Motion for Summary Judgment (memo not date/time stamped), p. 7.

<sup>111</sup> Dr. Singer and Hitchcock Clinic’s Reply Memorandum in Support of Motion for Summary Judgment (memo not date/time stamped), p. 8.

<sup>112</sup> Dr. Singer and Hitchcock Clinic’s Reply Memorandum in Support of Motion for Summary Judgment (memo not date/time stamped), p. 9, Footnote 13.



The defense exposed the inherent contradiction in the plaintiff's assertion that the inverted-V incision is different from the chevron because the former contains a corneal flap.<sup>114</sup> If this assertion were true, then the plaintiff's case against Singer would lose its central premise because Singer had also used a corneal flap after Pallin's patent had issued. Thus, with the plaintiff's thinking, Singer could not have infringed the Pallin patent. The defense also exposed the erroneous thinking in the plaintiff's assertion that because Gills used a corneal flap, he teaches away from the Pallin patent. The defense pointed out that Gills used the corneal flap after Pallin's first chevron and that the only consideration in refuting anticipation is the prior art.

The defense then turned to address the plaintiff's assertions about Gills' evidence:

“Recognizing that this prior art is fatal to his patent, plaintiff has engaged in a blunderbuss attack on Dr. Gills' sworn testimony, as well as the overwhelming corroboration of that testimony from Dr. Gills' surgical assistants, patient records, two published books, and a photograph of the actual incision used by Dr. Gills. . . . This character assassination of one of the leading eye surgeons in the country is completely groundless.”<sup>115</sup>

The plaintiff had previously discovered that Gills submitted a record of a patient which revealed a suture was used when sutureless surgery was claimed, but only one of the fourteen operating reports appended to Gills' declaration showed the use of a suture. The defense stated that the absence of detailed

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<sup>113</sup> Dr. Singer and Hitchcock Clinic's Reply Memorandum in Support of Motion for Summary Judgment (memo not date/time stamped), pp. 10-12, 15.

<sup>114</sup> Dr. Singer and Hitchcock Clinic's Reply Memorandum in Support of Motion for Summary Judgment (memo not date/time stamped), pp. 17-18 (See Footnote 26), 13 (Footnote 19). The defense laid to rest the issue of “perfect scleral flaps” by saying that the term merely refers to the roof of the scleral tunnel. Furthermore, the chevron incision method also contains these flaps.

<sup>115</sup> Dr. Singer and Hitchcock Clinic's Reply Memorandum in Support of Motion for Summary Judgment (memo not date/time stamped), p. 12.



notes did not invalidate the prior art of Gills, especially when corroborating evidence was present.<sup>116</sup> The defense reiterated case law which says that as long as an invention is used in its “natural and intended manner” and is not concealed, even if not accessible to the general public (e.g. operating room), it is considered to have been used publicly. The defense added that Gills reduced his invention to practice and did not abandon it because he disclosed it in lectures and books.<sup>117</sup>

Curiously, the defense wrote that it had informed the plaintiff that it possessed a photograph of Patient 208120, but the plaintiff pressed on.<sup>118</sup>

### *Obviousness defense*

The defense asserted that every feature described in Pallin’s 29 patent claims could be found in the surgical techniques described by Gills, Gillis, and Singer.<sup>119</sup> For anticipation, an invention in the prior art must contain every feature of the patented invention, but for obviousness, any number of inventions may each contain only one feature of the patented invention (provided these inventions were disclosed in a way that enabled practitioners in the field).

In mounting its obviousness defense again, the defense set primary considerations in a legal context rather than in a popular belief context as the plaintiff had been doing. The defense believed the plaintiff understood neither the legal test of obviousness nor the fact that patent claims supersede what he or anyone else publicly claims about the nature, workings, and scope of an invention.<sup>120</sup> Pallin claimed his invention was nonobvious because the ordinary ocular surgeon was not aware that sutureless surgery could be performed. But Pallin arrives at an erroneous conclusion because it is based on a mistaken premise. The legal test of obviousness asks if the hypothetical inventor with knowledge of all relevant prior art would have found the invention obvious, no matter how obscure the prior art is and even if it has not been

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<sup>116</sup> Dr. Singer and Hitchcock Clinic’s Reply Memorandum in Support of Motion for Summary Judgment (memo not date/time stamped), pp. 19 (Footnote 29), 20-21.

<sup>117</sup> Dr. Singer and Hitchcock Clinic’s Reply Memorandum in Support of Motion for Summary Judgment (memo not date/time stamped), pp. 19, 22.

<sup>118</sup> Dr. Singer and Hitchcock Clinic’s Reply Memorandum in Support of Motion for Summary Judgment (memo not date/time stamped), p. 14.

<sup>119</sup> Dr. Singer and Hitchcock Clinic’s Reply Memorandum in Support of Motion for Summary Judgment (memo not date/time stamped), p. 31.





disclosed.<sup>121</sup> Using this test, the hypothetical inventor on April 17, 1990, the day of Pallin's first chevron incision, would have found the chevron obvious because he would have known of the inverted V. Thus, the legal test of obviousness does not assess if an ordinary person in the art was aware of an invention. It assesses the intelligence, problem-solving ability, and ingenuity of an ordinary practitioner in arriving at the invention if provided with knowledge of all relevant prior art.

The defense also noted that while Pallin distinguished his incision by saying that it admits hard and soft lenses, this distinguishing feature is not mandated by the patent claims. Because patent claims and not testimonial statements are central to issues of patentability, the admission of different lens types is irrelevant to a discussion of nonobviousness.<sup>122</sup> The defense also noted that even though the techniques of others evolve over time, they are considered alternatives in the legal sense of obviousness.<sup>123</sup>

In evaluating secondary considerations, the defense noted that activity in the field of cataract surgery following Siepser's March 1990 presentation of his radial transverse incision renders Pallin's work obvious.<sup>124</sup> About two weeks after Siepser's presentation, the frown and inverted V incision methods came into being. By October 1990, Gills published a book on minimally invasive surgery, which included sections on sutureless incision techniques. According to the defense, other inventors of sutureless incisions did not know of Pallin's work. Pallin's claims of the commercial success of his sutureless incision are baseless when one observes that the source which Pallin is citing says that 1/3 of ophthalmologists were now using the "frown" incision (not necessarily denoting Singer's incision).<sup>125</sup> Although Pallin claims he met a long unmet need in the field of cataract surgery, that need was already fulfilled by others before

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<sup>120</sup> Dr. Singer and Hitchcock Clinic's Reply Memorandum in Support of Motion for Summary Judgment (memo not date/time stamped), pp. 24, 26-27.

<sup>121</sup> Dr. Singer and Hitchcock Clinic's Reply Memorandum in Support of Motion for Summary Judgment (memo not date/time stamped), p. 24.

<sup>122</sup> Dr. Singer and Hitchcock Clinic's Reply Memorandum in Support of Motion for Summary Judgment (memo not date/time stamped), pp. 26-27.

<sup>123</sup> Dr. Singer and Hitchcock Clinic's Reply Memorandum in Support of Motion for Summary Judgment (memo not date/time stamped), p. 26, Footnote 34.

<sup>124</sup> Dr. Singer and Hitchcock Clinic's Reply Memorandum in Support of Motion for Summary Judgment (memo not date/time stamped), pp. 27-29.

<sup>125</sup> The annual Leaming survey determines trends in the fields of ophthalmology, including changes in the use of cataract surgery techniques. See pp. 461-2 of the 1990 Leaming survey in Plaintiff's appendix of exhibits. Although the survey mentions the "frown" incision, it does not appear to be a reference to Singer's incision. Rather, it appears to be a generic reference to an incision that diverges away from the limbus.



April 17, 1990. The defense stated that the plaintiff had not proven that the incisions of others did not work. The defense also stated that while the failure of others can lead to an inference of nonobviousness, the success of other inventors can lead to an inference of obviousness.

The defense crystallized its obviousness argument in three points.<sup>126</sup> First, the work of Gills would render Pallin's incision method obvious to the hypothetical inventor in the field. Second, the solution of moving an incision closer to the limbus to prevent "oarlock" effect would be obvious to a person of ordinary skill in the art. Third, the defense noted that the plaintiff did not dispute that adding curvature to the prior art of Gills would be an obvious alternative. The defense concluded:

"Defendants respectfully submit that it is time to bring this baseless case to an end. Plaintiff is not entitled to a twenty-year patent monopoly, nor is he entitled to seek money damages from doctors who have the temerity to use "his" surgical technique to improve the vision of their patients. Because plaintiff's claimed invention was both anticipated and obvious he is not entitled to monopolize its teaching and use for the next twenty years."<sup>127</sup>

At the conclusion of the Markman hearing on March 28, 1996, nearly three years after Pallin's attorneys filed a complaint alleging patent infringement by Singer and the Hitchcock Associates of Randolph and after months of professional society outrage and lobbying, political wrangling in Congress, and a protracted legal war, Judge Sessions decisively brought the case to an end by issuing the following consent order:

"It is hereby ordered that:

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<sup>126</sup> Dr. Singer and Hitchcock Clinic's Reply Memorandum in Support of Motion for Summary Judgment (memo not date/time stamped), pp. 30-31.

<sup>127</sup> Defense counsel errs in writing that Pallin has a twenty-year patent monopoly. The term of Pallin's patent is 17 years. In 1995, patent law was modified to extend the term of a patent from 17 to 20 years.



1. All of the patent claims at issue in this case are declared invalid.
2. Plaintiff will take no action to enforce any feature of the patent against the parties, any physician, health care provider, hospital, clinic, teaching institution, or other entity or person of any kind.
3. It is hereby declared that neither The Hitchcock Clinic, d/b/a The Hitchcock Associates of Randolph, nor Jack A. Singer, M.D., infringed Patent Number 5,080,111 in any respect.
4. This action is hereby dismissed with prejudice. Each side shall bear its own fees and costs.”<sup>128</sup>

Pallin’s patent was effectively nullified because he could no longer enforce it.



## XIV. Fallout

Although *Pallin v. Singer* ended with Judge Sessions' consent order, the controversy over patenting medical methods continued. Pallin's lawsuit against Singer sparked debate and activity in the medical profession, the Congress, and the PTO (See Chronology).

### Retrospective: Pallin & Singer on *Pallin v. Singer*

#### *The Case*

- Enlightening details

In interviews conducted two years after *Pallin v. Singer* ended, both Pallin and Singer offered enlightening details of their legal case. With respect to patent strategy, Pallin offers curious remarks. Pallin says he and his attorneys knew from the beginning that it would be difficult to collect royalties because each infringing physician would require an individual case. In their view, "we knew it was not practical to collect royalties. And there was every likelihood that we would fail in collecting royalties because we expected every doctor in every medical society to fight us."<sup>1</sup> Then, it is curious why Pallin would even embark on the pursuit of royalties in the first place.<sup>2</sup> He must have believed that he could succeed in collecting royalties from a few doctors. Perhaps if he could obtain fees from or win one case against a prominent or formidable opponent, the precedent would strengthen his patent enforcement ability. Or, two years after the case ended, this explanation was his way of dulling the blow of his legal defeat and softening his image as a rogue physician who demanded license fees from a colleague.

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<sup>1</sup> Transcript of Interview with Dr. Samuel Pallin at his home in Scottsdale, Arizona (Interview conducted by B. Rengarajan), April 24, 1998, p. 15.

<sup>2</sup> Pallin says the royalty rate of \$5 that he had mentioned in the Congressional hearing was referenced with an industry standard and chosen to maximize collections<sup>2</sup>. He claims that he sought a royalty fee that physicians could pay, given they "had enough trouble and [he and his attorneys] didn't want to make it difficult for them to pay it," and royalty fee that was small enough to yield a successful collection rate. According to Pallin, five percent was the standard royalty rate in medically-allied industry. At the time Pallin derived his royalty rate, he says the cost of a cataract operation was about \$1,000. Thus, his royalty rate was 0.5%, less than the standard.





Pallin did send cease-and-desist letters to local ophthalmologists who were advertising sutureless incisions and not giving him credit in their advertisements.<sup>3</sup> However, his first demand for a license fee was against Singer and the Hitchcock Associates of Randolph. When asked why he did not target a weaker player than the Hitchcock Clinic, Pallin replied, “That would be cowardly.”<sup>4</sup> But, it appears that Pallin and his attorneys did not know that the Hitchcock Clinic consisted of over 800 physicians and possessed the resources to engage in costly litigation.<sup>5</sup> The more convincing reasons for targeting Singer would appear to be that Pallin resented Singer for taking credit for developing the incision and Singer had developed an incision quite similar to the chevron incision. If Pallin could defeat Singer, he would have built a strong precedent.

Yet in an effort to avoid going to court, Pallin says he made several one-dollar license offers to the defense contingent on their recognizing the validity of his patent.<sup>6</sup> Even though the plaintiff gradually revised the license offer from \$2,500 -- \$10,000 per year to a free lifetime license in exchange for dropping counterclaims (i.e. charge of patent invalidity), Singer refused as a matter of principle.<sup>7</sup> He feared that accepting any concession that would leave Pallin’s patent intact would encourage Pallin to enforce his patent against other physicians with demands for injunctions and “anything he wants.”<sup>8</sup> Pallin believes the defense refused a license because it wanted to prove its point, even as he wanted to prove his own point.<sup>9</sup>

Singer says no one was using Pallin’s incision technique. He adds that the frown-style incision was being used to eliminate surgically-induced astigmatism, not to eliminate sutures. Singer says Pallin was “way off base” with his desire to collect royalties from physicians who were using sutureless incisions with internal corneal lips because Pallin did not initially use a corneal lip.<sup>10</sup> Singer reports that Pallin now uses a corneal lip even though he does not believe it is required for self-sealing and does not mention it in

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<sup>3</sup> Pallin says he wrote to three local ophthalmologists informing that they should not be advertising sutureless incisions without giving Pallin credit. Pallin says two of them became angry, and the third sent a letter to Pallin stating he thought Pallin’s patent was invalid. Pallin interview, p. 8.

<sup>4</sup> Pallin interview, p. 15.

<sup>5</sup> Transcript of Interview with Dr. Jack Singer at his clinic in Randolph, Vermont (Interview conducted by B. Rengarajan), June 26, 1998, p. 6.

<sup>6</sup> Pallin interview, pp. 14-15.

<sup>7</sup> Singer interview, p. 5.

<sup>8</sup> Singer interview, p. 6.

<sup>9</sup> Pallin interview, p. 15.

<sup>10</sup> Singer interview, p. 7



his patent.<sup>11</sup> This begs the question why Pallin would use a corneal lip if he believes that it does not lead to incision closure. The answer to this is not known, but Singer believes the internal lip is necessary for safe elimination of the suture. He speculates: “Of course, if you pump the eye up hard enough with fluid at the end of the case, it will seal, which is probably what Pallin is doing with his incisions.”<sup>12</sup> Nevertheless, Singer states that Pallin’s belief and teachings on the internal lip are not accepted as safe procedure in the field. He says the defense could have pursued a strategy of showing that a corneal lip is required for safe sealing, but this route would have been more difficult than the anticipation route the defense did take.<sup>13</sup>

Pallin believes two of the witnesses at the hearing lied when they claimed that the surgical limbus was an unreliable landmark and that the better landmark was the vascular arcade.<sup>14</sup> Pallin says this claim is false and would not be found in any textbook. Pallin believes the witnesses lied on the witness stand because they wanted to distinguish their incisions from his in order to escape infringement. However, by the time witnesses were put “on the stand,” the *Markman* hearing was taking place. At this point in the case, the issue was anticipation, not infringement. This suggests that Pallin does not have his facts straight or he is attempting to recast himself as a victim of liars.

Pallin will not agree that his patent was invalidated, but he will concede that he was unable to enforce the patent.<sup>15</sup> Pallin says other medical patenting controversies did not help him. He specifically raises the case of Dr. Mark Stephens’ patent on determining the sex of a fetus, which he believes to be a shady controversy. Pallin has heard that Stephens is not well-respected. Pallin distances himself from the likes of Stephens:

“I’ve always been really honest about all of this, and I don’t think it’s reflected poorly on me except in certain medical circles. I guess I lost

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<sup>11</sup> During the case, Pallin had presented a videotape of a surgery in which he did not use an internal corneal lip. Singer reports that the incision sealed without a suture, and the patient did well (Singer interview, p. 3). Pallin offers the video as proof that an internal lip is not necessary for incision sealing.

<sup>12</sup> Singer interview, p. 3.

<sup>13</sup> Singer interview, p. 3.

<sup>14</sup> Pallin interview, p. 18.

<sup>15</sup> Pallin interview, p. 20.



a few friends over it. The public has always been supportive. The community has been supportive.”<sup>16</sup>

- How the case was settled

Although *Pallin v. Singer* ended crisply with a consent order prohibiting Pallin from enforcing the remaining claims of his patent, the events of the Markman hearing are not precisely clear.<sup>17</sup> From available information, Pallin and Singer hold different interpretations. However, the balance of evidence lends more credibility to Singer’s account.

Pallin believes a trial could have been decided either way, but Singer maintains that the defense had built a winning case. Although Pallin admits it would have been “very damaging” had Gills performed the same technique that he had, he maintains that Gills did not have a clear idea of what he was doing.<sup>18</sup> Pallin believes he received a “bad deal” because Judge Billings had sent the case to trial but the case was returned to pre-trial status per *Markman*. Also, according to Pallin, Judge Sessions possessed no patent case experience. Finally, Pallin had to face a well-equipped and formidable opponent.<sup>19</sup> Of his opponents, Pallin said:

“You’re talking about people who got a law passed in the United States Congress. These people don’t fool around. Fortunately, they don’t hire, you know, killers. But politically they do. They threw everything at me they could.”<sup>20</sup>

In Singer’s account, Dr. Ernest pointed out during the Markman hearing that Singer had never infringed Pallin’s patent because in his efforts to create an internal corneal lip he had moved his incisions

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<sup>16</sup> Pallin interview, p. 20.

<sup>17</sup> Although stenographic notes for the Markman hearing exist, a complete transcript of the hearing does not. As of June 1998, a complete transcript had never been requested of the court stenographer. This author did not request a complete transcript because it would be prohibitively expensive.

<sup>18</sup> Pallin interview, p. 16.

<sup>19</sup> Pallin interview, p. 15.

<sup>20</sup> Pallin interview, p. 15.



to a distance of one millimeter behind the limbus apparently before Pallin's patent was issued. On the witness stand at the *Markman* hearing, Pallin could not counter this point with any evidence of infringement. Judge Sessions urged the opposing parties to settle. Judge Sessions never had to consider Gills' photo of Patient 208120 or the defense's second motion for summary judgment.

On the subject of settlement, Pallin and Singer again offer different interpretations. Pallin correctly states that he continues to hold U.S. Patent #5,080,111, but he claims that he simply agreed not to charge royalties.<sup>21</sup> Pallin claims that he did not want to pursue this case any longer even though his attorney was prepared to appeal.<sup>22</sup> Singer claims that Pallin had no choice but to sign the consent order, which was drafted by the defense attorneys. In Singer's account, the defense possessed evidence that Pallin had violated the law in not disclosing to the PTO prior art of which he was aware. Singer added that Pallin knew if he lost at trial, he might be liable for the legal expenses of the defense.<sup>23</sup>

Pallin believes the defense did not attempt to invalidate his patent fully because it did not have a solid case, and he speculates, because the Hitchcock Clinic wanted the case disposed of expediently after it was no longer liable for paying royalties.<sup>24</sup> On the other hand, the ASCRS wanted to invalidate his patent fully, but it did not have the standing in the case to decide that. Pallin believes the defense was confident about winning, but he questions if the defense could repeat its feat under different circumstances:

"I think they knew they were getting a fairly good judge. They had a very expensive, very resourceful legal firm hired. I think it was pretty well set up. And they knew they could win, and they did. But I'm not sure they could do it again. I don't think they were sure they could do it again, given a different judge and so on. And maybe a jury trial.

Don't forget there would be a jury trial."<sup>25</sup>

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<sup>21</sup> Pallin interview, p. 16.

<sup>22</sup> Pallin interview, pp. 18-19.

<sup>23</sup> Singer interview, pp. 3-4.

<sup>24</sup> Pallin interview, p. 17.

<sup>25</sup> Pallin interview, p. 17.





Singer says the defense did not pursue complete patent invalidation because it had achieved its objectives and preferred to advocate legislative change:

“Legally, we couldn't invalidate the whole patent at the hearing. But we forced him to sign a consent order stating that he will not enforce that patent against any entity of any kind. So we effectively nullified the patent, made it worthless. In order to specifically invalidate all of the claims of the patent, we would have to go to a trial. And that would be very costly. It was felt that enough money was spent. We just let it go there. We achieved our goals. And we then focused the resources of the profession to lobby for the patent law change.”<sup>26</sup>

Although the ending of *Pallin v. Singer* is not completely clear, it would seem that the court was presented with a strong case to invalidate Pallin's patent. However, when it was discovered that Singer had not even infringed Pallin's patent, Judge Sessions urged both sides to settle. Pallin did not mention the absence of infringement during his interview. Considering the plaintiff's previous persistence in pushing the case toward trial and his assessment that the legal outcome could have gone either way, it is unlikely that he would sign a consent order which invalidates the four claims at issue and enjoins him from enforcing the remaining claims of his patent, unless his hand was forced. Even more deterring than the prospect of paying the defense's legal expenses or having his entire patent invalidated if he lost at trial must have been the prospect of facing criminal charges for not disclosing to the PTO prior art of which he was aware. Afterwards, it appears Singer and the Hitchcock Clinic redirected resources toward lobbying Congress.

#### *Post-Pallin v. Singer*

- *Markman*

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<sup>26</sup> Singer interview, p. 5.



The *Markman* case was appealed to the U.S. Supreme Court on January 8, 1996. Had the previous Court of Appeals for the Federal Circuit (CAFC) ruling been overturned, the *Markman* hearing in *Pallin v. Singer* would have been rendered moot, and the case would have moved to trial. Singer questions the veracity of Pallin's February 1996 letter to the court in which he reports sustaining a shoulder injury which might preclude his presence at the *Markman* hearing.<sup>27</sup> Because Pallin participated in the *Markman* hearing in March 1996, Singer views the injury report as a delaying tactic to allow time for the Supreme Court ruling, which could have overturned *Markman*.

On April 23, 1996, just weeks after the *Markman* hearing and settlement of *Pallin v. Singer*, the Supreme Court unanimously upheld the lower court's verdict in *Markman*.<sup>28</sup> In his opinion for the Court, Justice David Souter wrote that the issue to be resolved by the Court was not the requirement that a patent infringement case must be tried before a jury as guaranteed by the Seventh Amendment of the U.S. Constitution. Rather, the issue to be resolved was whether a particular issue in the trial – construction of patent claims – is an issue for the jury. The historical record supported the role of judges, not juries, in construing patent specifications. Souter wrote: "Since evidence of common law practice at the time of the Framing does not entail application of the Seventh Amendment's jury guarantee to the construction of the claim document, this Court must look elsewhere to characterize this determination of meaning in order to allocate it as between judge or jury." The Court looked to legal precedent, the relative skills of judges and juries, and statutory policy. The Court stated that nineteenth-century juries appear not to have resolved the meaning of patent claims. In its view, it was better to have judges construe claims because of their training in interpreting highly technical patents. Finally, the desire for uniformity in adjudicating patent issues favors a role for the courts.

- Perceptions on the PTO

Pallin and Singer disagree on the ability of the PTO to handle medical patents. Pallin expresses faith in the patent system. He believes the nonobviousness requirement of patent law disallows many

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<sup>27</sup> Singer interview, p. 4 and 2/27/96 Letter from Pallin to White. Copy filed with U.S. District Court of Vermont on 2/29/96.

<sup>28</sup> *Markman v. Westview Instruments*, 517 U.S. 370, 116 S. Ct. 1384, 38 U.S.P.Q.2d 1461.



patents at the level of the PTO. He notes, however, that inventions are often considered obvious after patents are issued:

“Nobody thought my patent was obvious, except after the fact. After the fact, when you get a patent, everybody thinks it’s obvious – “Oh, I could have done that. We do that every day.” And that’s true with every patent.”<sup>29</sup>

He believes the PTO can appropriately handle medical patents. He points out that the PTO reviews patent applications in every industry and must by necessity be competent. Pallin believes physicians are making baseless arguments when they charge that the PTO is not well-equipped to deal with medical patents:

“think about this: these are the guys that pass on genetic engineering and molecular biology. They’re not competent to pass on an incision? Give me a break. They know how to do their research. They caught a lot of hell for it, and they’re not happy over there [at the PTO]. The guy who was responsible for testifying at the hearing,...he said to me: “Dr. Pallin, couldn’t you guys have settled this among yourselves? Don’t doctors have a way to settle these things?””<sup>30</sup>

Singer would beg to differ.<sup>31</sup> He believes the PTO cannot remedy its alleged poor performance in reviewing medical method patents because the Office cannot keep abreast of physician communications over the Internet. Singer cites professional society mailing lists and personal emails between colleagues as examples. However, Singer does not acknowledge that personal or informal emails may not constitute public disclosure and therefore would not contribute to considerations of novelty at the PTO. When asked

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<sup>29</sup> Pallin interview, p. 23.

<sup>30</sup> Pallin interview, p. 24. The “guy” is probably G. Lee Skillington, Counsel for Legislative and International Affairs at the PTO.



what is the difference between the PTO's handling of medical method patents and its handling of early patents in the young and rapidly-moving biotechnology and computer software fields, Singer appeared to deflect the question by simply replying that physicians normally do not seek patent protection. Singer thinks changing PTO practices to solve the problem of medical method patents is moot because, in his view, it is unethical for doctors to obtain patents on medical methods.

- Thoughts on legislation

Pallin and Singer do agree that the fact that the sponsors of the bills to limit medical method patents were physicians was not important in the passage of Section 616 of Public Law 104-208. However, they hold different interpretations of why the provision was passed. Pallin believes that the prohibition on the enforcement of medical method patents passed because the medical lobby did not have more pressing issues to address and Congress was looking to appease the medical community in a year in which it was looking to cut Medicare spending.<sup>32</sup> Pallin thinks the provision would not have passed in any other year.

Considering that Representative Carlos Moorehead, the chairman of the House Subcommittee on Courts and Intellectual Property, opposed limitations on the patenting of medical methods, Pallin declares that the current ban will be repealed, particularly if a Republican administration emerges.<sup>33</sup> In Pallin's view, the reason for repealing would not be an inherent respect for the uniform application of patent law. Instead it would be foreign policy, although he stated that he thought Representative Ganske and Senator Frist genuinely believed the ban was in the best interests of the medical community. Stating that the U.S. has been engaged in an intellectual property war for many years with pirating countries such as China, Pallin places the issue in perspective:

“Our country, in its foreign policy, has an espoused goal of strengthening intellectual property protections around the world and especially with our big trading partners, and here we just suddenly did

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<sup>31</sup> Singer interview, pp. 7-8.

<sup>32</sup> Pallin interview, p. 21.

<sup>33</sup> Pallin interview, pp. 21-2.





an about-face and changed the law in the United States to weaken intellectual property ownership. And the interesting thing you see in the debate also, the medical side frequently refers to the fact that many of the countries in the Western world do not allow medical patents, and that's true. But what they have neglected to put in print is that these countries are behind the United States. The United States, at one time, never had any protection for medical property either. And they've just never evolved to that point. It's not that they outlawed it. They never could. The United States would like them to include it. The United States would like nothing better than for France and Germany and Switzerland and the other countries of the western world to honor our medical methods and devices."<sup>34</sup>

Singer believes Congress prohibited the enforcement of medical method patents because it believed such patents were detrimental to health care access, cost, and quality. He thinks the enforcement ban, as well as the outcome of *Pallin v. Singer*, will deter physicians from trying to enforce medical method patents.<sup>35</sup>

- Pursuit of Pallin

When Judge Sessions urged both sides to settle, Pallin says he demanded one condition for settling the case.<sup>36</sup> He wanted to continue to claim inventorship of the chevron incision and to represent this in advertising and in his public persona. According to Pallin, the defense said he could do as he pleases. But this proved not to be the case.

On May 24, 1996, the American Society of Cataract and Refractive Surgery (ASCRS) filed complaints with the Federal Trade Commission, the Attorney General of Arizona, and the Arizona Board

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<sup>34</sup> Pallin interview, p. 22.

<sup>35</sup> Singer interview, p. 10.

<sup>36</sup> Pallin interview, p. 19.



of Medical Examiners, alleging that Pallin had engaged in deceptive advertising.<sup>37</sup> The advertisement at issue appeared in the May 13, 1996 issues of the *Arizona Republic* and *Phoenix Gazette*. The advertisement claims that Pallin invented “Chevron no-stitch cataract surgery” and that he holds “the United States patent for no stitch cataract surgery.” The complaints alleged that Pallin did not invent Chevron no-stitch cataract surgery, it is misleading to “boast about holding a patent on a surgical procedure when the principal features of that patent have been invalidated and when he had been enjoined from enforcing any aspect of that patent,”<sup>38</sup> and advertising ownership of a patent can mislead patients into believing the government has granted a seal of approval on the patented technique. The ASCRS also stated that it was against its Society’s guidelines to claim ownership of a patent through advertising. Singer likened Pallin’s advertising to “claiming to have the world’s fastest race car without mentioning that the car has no engine and no wheels.”<sup>39</sup>

The ASCRS portrayed Pallin as untrustworthy. It said that Pallin had misled the public when he stated that his patent had “withstood a stiff legal challenge” when in fact he had been enjoined from enforcing his patent. The ASCRS kept a close eye on Pallin; in an April 1996 press release, it wrote:

“Anyone with information about attempts to enforce any aspect of Patent No. 5,080,111, either by Dr. Pallin or anyone else, should immediately contact ASCRS so that it may initiate contempt proceedings or take other appropriate legal action.”<sup>40</sup>

Pallin says that the FTC and the Attorney General of Arizona did not pursue the complaint. Under enormous political pressure, the Arizona Board of Medical Examiners considered disciplining Pallin but

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<sup>37</sup> --. “ASCRS Files Complaint Over Deceptive Advertisements by Samuel Pallin, MD Regarding Invention of Sutureless Surgery,” *PR Newswire*, May 24, 1996.

<sup>38</sup> The argument is not completely valid because although four claims of Pallin’s patent were invalidated, only two of them were independent claims (claims 1 and 22). The Pallin patent still possesses two intact independent claims (claims 9 and 19) with associated dependent claims, which together cover the performance of the chevron incision. Thus, some “principal features” are still intact. However, at the conclusion of *Pallin v. Singer*, Pallin was enjoined from enforcing his patent.

<sup>39</sup> Singer, J. Comments in email note (provided by Singer), May 10, 1996.



eventually decided not to do so.<sup>41</sup> The Board informed Pallin that a consumer might mistake the breadth of the Pallin patent from reading the advertisement because the patent covers an incision method, not a complete operation. Pallin says the issue was resolved when he volunteered to use the word “incision” in lieu of “operation.” As to why the ASCRS aggressively pursued this matter, Pallin stated:

“I have told you there are many conflicts-of-interest in that organization. I think they were trying to destroy me, destroy my practice, my reputation. They have not succeeded because I always tell the truth.”<sup>42</sup>

### *Final Thoughts*

If it had to be played out again, Pallin says he probably would have obtained the patent, but he might not have enforced it because it consumed too much time and generated difficult criticism, “some of it untrue and painful, some of it coming from areas where I considered I had friends.”<sup>43</sup> Pallin’s greatest concern is his belief that the AMA is unfairly applying a double standard in prohibiting physicians from patenting medical methods but allowing non-physicians to patent the same.<sup>44</sup>

If Singer had to go through this process again, he says he would have challenged Pallin’s patent at the PTO.<sup>45</sup> However, The Hitchcock Clinic decided to wait and see what Pallin would do. Legal costs for Singer and the Hitchcock Clinic amounted to approximately \$500,000.<sup>46</sup> Singer hopes the prohibition on enforcement of medical method patents will hold.

### State-of-the-art Cataract Surgery

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<sup>40</sup> American Society of Cataract and Refractive Surgery, “Pallin Patent Claims Invalidated: Part II,” (Press Release) April 2, 1996.

<sup>41</sup> Pallin interview, p. 19.

<sup>42</sup> Pallin interview, p. 20.

<sup>43</sup> Pallin interview, p. 23.

<sup>44</sup> Pallin interview, p. 21.

<sup>45</sup> Singer interview, p. 10. Singer could have requested a reexamination proceeding in which he could present prior art. Alternatively, he could have filed a formal protest while the PTO was examining Pallin’s application.



Although Pallin agreed to not enforce his patent, a number of recent and future developments stand to make enforcement of his patent moot. In the early 1990s, many cataract surgeons began to make their incisions into the cornea directly, avoiding the sclera. One estimate places corneal incisions at 30% of cataract surgeries in 1998.<sup>47</sup> Patients are usually more comfortable, and surgeons can perform cataract extraction more rapidly. Corneal incisions bypass Pallin's patented invention and the similar scleral incision techniques of McFarland, Ernest, Siepser, Gills, and Singer. Singer himself had moved his incisions into the cornea by 1992. Thus, Pallin's patent could have been rendered moot in a short time. The rapid pace of innovation in fields such as ophthalmologic surgery can quickly render innovations, inventions, and *patents* moot.<sup>48</sup>

The mechanism of incision self-sealing is still debated today.<sup>49</sup> Considering that many surgeons have reduced incision size to slightly below three millimeters, the issue may already be moot. Incisions which are 2-3 millimeters in length tend to seal by themselves. The debate may not be relevant today, but it played a large role in *Pallin v. Singer*. The question of self-sealing mechanism might have more than one answer, as Singer himself indirectly suggests when he speculates that Pallin may have been sealing incisions by pumping fluid into the eye at high pressure at the end of a case.<sup>50</sup> Alternatively, the corneal lip may also achieve self-sealing.

Experimental methods stand to reduce or displace surgical methods.<sup>51</sup> Although requiring a small incision, lasers will be used to dissolve cataracts. Another method involves the injection of an enzyme to dissolve the lens followed by injection of polymer to reconstitute the lens. Charles Kelman has discussed implanting in the lens plastic blades which can be made to spin when placed in a magnetic field.<sup>52</sup>

#### Changes at the Patent and Trademark Office

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<sup>46</sup> Singer, J. Comments in email note (provided by Singer), May 10, 1996.

<sup>47</sup> Weitzman interview, p. 2.

<sup>48</sup> Singer testified before Congress that an eye surgery method can be developed in 6-12 months in an environment of free dissemination of knowledge. Hearing, p. 44.

<sup>49</sup> Weitzman interview, pp. 2-3.

<sup>50</sup> Singer interview, p. 3.

<sup>51</sup> Weitzman interview, p. 1.

<sup>52</sup> Weitzman interview, p. 7





While *Pallin v. Singer* was in progress, the PTO accelerated its ongoing efforts to improve its practices in the medical methods area.<sup>53</sup> The PTO hired medical professionals, created a new art unit for medical methods within the larger medical devices group in 1995, and reduced the workload of examiners reviewing medical method inventions. The PTO also trained examiners in database searching. Some of the recommendations made by participants in the May 1996 PTO hearing had already been implemented at the PTO, but Congress enacted the ban on enforcement of medical method patents just a few months after the hearing. The PTO has always had to adapt to changes in inventive activity, and it will continue to do so.

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<sup>53</sup> PTO examiner interview, April 1998, p. 5.



## XV. Conclusion

*Pallin v. Singer* occurred because Pallin's patent application was poorly reviewed (because Pallin did not disclose prior art and the examiners did not search medical journals for prior art), Pallin aggressively enforced his patent, and Singer and the Hitchcock Clinic refused to compromise. However, the milieu in which this case occurred also played a role. The AMA allowed physicians to patent medical inventions, but its position on patent enforcement was not clear. Physicians had been enforcing product patents for years. Finally, medicine and the biotechnology industry had been undergoing commercialization.

The story of *Pallin v. Singer* shows that the conception of an invention can be defined iteratively by a lawsuit and that legal conflict is almost inevitable when the values of the principals are diametrically opposed. As participants in the lawsuit struggled to compare and contrast incision methods, it became apparent that patents like any other constructions of the law are subject to interpretation. A capsule summary of the case and the controversy it created illustrates the significant themes and turning points that shaped its course.

### Capsule

In April 1990, Pallin developed the chevron sutureless incision technique for cataract surgery. He wanted credit for his work and therefore submitted an article for publication, but his manuscript was rejected.<sup>1</sup> Consequently, Pallin applied for a patent which was granted in January 1992. It is not clear if Pallin had intended to secure a patent all along, but it is clear that he wanted to derive an income from licensing his patent. In 1993, Pallin sued Singer and the Hitchcock Associates of Randolph because he resented Singer for taking credit for the incision technique and because he could build a credible licensing precedent if Singer would purchase a license. The frown incision was similar to the chevron incision, and it fell under the purview of Pallin's patent. The defendants refused to purchase a license on moral grounds and demanded the dedication of Pallin's patent to the public. This position prevented the case from being settled.



The plaintiff sought a judicial stamp of approval for his patent, and the defense sought to invalidate his patent. As the case became more technical, other sutureless incision techniques came to light. Pallin's sutureless incision work was not the first. The case shifted from infringement to anticipation. However, no one surgeon had anticipated every feature of Pallin's technique, and the credibility of the work of Gills, which was emerging as the centerpiece of the defense's case, was questionable. As the credibility of Gills and his evidence waxed and waned with every legal brief submitted, Pallin was entangling himself in a web of inconsistent and contradictory statements. Judge Billings denied the defense's summary judgment motion for a ruling of patent invalidity because the defense failed to address secondary considerations of nonobviousness and because "complex factual disputes" existed over prior art, particularly the credibility of Gills' measurements of incision distance.

Relying on the *Markman* precedent, the defense redirected the case from a jury trial to a two-day hearing to resolve issues over interpretation of patent claims. The defense reinforced and solidified its arguments. Four key issues emerged and converged toward the end of the case: credibility of Gills and Pallin, patent interpretation, prior art, and nonobviousness. The flurry of sutureless incision development that occurred after Siepser's March 1990 presentation of his sutureless radial T incision and the prior art of Gills (inverted V incision) stood to invalidate Pallin's patent. The anecdotal report of McFarland's sutureless incision work predating Siepser's presentation and the 1991 *Journal of Cataract and Refractive Surgery* Supplement issue, entitled "Small Incision Surgery: Wound Construction & Closure," which contained numerous articles on sutureless incisions, only bolstered the obviousness of Pallin's invention. Whatever remained of the infringement component of the case evaporated with the discovery that, technically, Singer had not even infringed Pallin's patent. With the prospect of being liable for the defense's trial expenses and being criminally prosecuted for non-disclosure at the PTO, Pallin was forced to sign the consent order which invalidated the patent claims at issue and enjoined him from enforcing the remaining claims in his patent. Ironically, it was Dr. Jim Gills who sparked Pallin's exploration for a watertight and sutureless incision. And it was Dr. Jim Gills who emerged as the centerpiece of the legal campaign to invalidate Pallin's patent on a watertight and sutureless incision.

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<sup>1</sup> Of note, Pallin submitted his report to only one journal.



Meanwhile, the medical profession reacted negatively to the case. The AMA and the ASCRS assumed leadership in addressing issues raised by *Pallin v. Singer*. They opposed the patenting of medical methods because they thought it would hinder patient care, decrease professionalism, and increase health care costs. But the AMA had difficulty reconciling its ethical acceptance of the patenting of medical products by physicians and its opposition to the patenting of medical methods by physicians. The AMA crafted a dubious distinction in saying that the patenting of medical products is justified because of high R&D expense and the patenting of medical methods is not justified because methods are cheaply developed in the course of clinical practice. A significant majority of the arguments used against patenting medical methods can also be used against patenting medical products. Separating products and methods in the context of patents is not always possible. Ultimately, the AMA employed an economic justification for an ethical position that was illogical, inconsistent, and unfair.

What motivated Congress to legislate on medical method patents is a trickier issue. The Medical Procedure Patents Coalition, which included the AMA, was lobbying Congress. At the same time, Congress was considering Medicare budget cuts, which angered the medical community. This probably increased the need for placating gestures. But Representatives Moorehead and Schroeder, the chairman and ranking member respectively of the House Subcommittee that held hearings on H.R. 1127, opposed the proposed ban on medical method patents. And legislators were well aware of the implications of adopting patent system restrictions on the U.S. position in negotiating trade-related aspects of intellectual property (TRIPs) with other nations. Although Pallin and Singer do not find the fact that two of the bill sponsors were physicians to be important, these two legislators may have lent credibility to the proposed legislation and a sympathetic point of access for the Medical Procedure Patents Coalition. Most legislators have law backgrounds, and it is probably fair to say that lawyers and judges believe in the integrity and consistent application of the laws. They knew that atomic weapons and other inventions that jeopardized national security constituted the only exemption from patentable subject matter. Although the legislation that ultimately passed only banned enforcement, it is effectively a partial statutory prohibition on medical method patents because such patents cannot be enforced against a particular group (health care providers).





Perhaps Pallin was right. The only carrot Congress could offer the medical community in that year was the passage of the enforcement ban.<sup>2</sup>

Meanwhile, the PTO held hearings on patent protection for medical methods. Even preceding the end of the *Pallin v. Singer* or passage of the enforcement ban, the PTO improved its examination practices by searching medical journal databases, creating a new art unit to review medical methods, and hiring physicians.<sup>3</sup> The PTO is probably applying the law correctly. In the case of Pallin's application, it did not have access to relevant prior art, which it is now much better-equipped to obtain.

Despite the passage of Public Law 104-208, the enforcement ban would not have applied to Pallin's patent. Ironically, by enforcing his patent, Pallin lost the right to enforce it.

### Comment

One might ponder the enormous number of alternate scenarios that might have played out if Pallin were the first to invent a sutureless incision technique, if his article had been published, and if he had not charged royalties. What would have happened if Singer had used small lenses (<6mm diameter) for his first few incisions? If the Hitchcock Clinic and the ASCRS had chosen not to support Singer? If Pallin's patent had been written more precisely? If all 29 patent claims had been at issue? If the case had gone to trial? The answers are speculative, but the end result probably would have been essentially the same. Pallin's patent was not strong, and organized medicine committed itself to eliminating or limiting medical method patents. Pallin was unwise in continuing to litigate a weak patent in the face of overwhelming evidence supporting its invalidity, but he was heroic in defending the patent system and questioning the AMA's dubious stance on patenting medical methods.

The prohibition on the enforcement of medical method patents, although less troublesome than a prohibition on medical method patents, constitutes poor precedent. Proponents of the enforcement ban claim that the costs of patenting outweigh its benefits, and their opponents maintain the opposite view. However, the proponents do not appear to consider what is perhaps the largest cost of restricting medical method patents, which is creating a precedent for particular groups to claim special status under the law.

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<sup>2</sup> Pallin interview, p. 22.



One could argue that uniform and consistent application of the law is the most important principle to keep in mind. If this principle goes unheeded, the cost of such a precedent may be greater than any benefits of an enforcement ban.

Singer and his allies can make a strong case for prohibiting medical method patents, but the environment is not changing in their favor. Medicine and biotechnology continue to undergo commercialization, not only with respect to devices and drugs but also with respect to care provision and payment. Pharmaceutical and managed care companies continue to commercialize and corporatize medicine. The environment only seems to become riper for patenting medical inventions.

It is unclear how the views of the medical profession on patenting medical methods will change, if at all. But the AMA which initially opposed the patenting of medical inventions by physicians eventually came to accept and perhaps even encourage such activity. It is highly doubtful the AMA will move in the opposite direction.

### Implications

Even though *Pallin v. Singer* ended and Congress banned the enforcement of medical method patents, there exists the potential for further controversy in medical method patents which were granted before the enforcement ban was passed. These patents, such as the ones held by Dr. John Stephens for determining the sex of a fetus,<sup>4</sup> Men's Health Resources (MHR) for treating impotence with penile drug injections, and Dr. Mark Bogart for using maternal hormone levels to predict the occurrence of Down's Syndrome, as well as others that might be waiting in the wings, have the potential to cause controversy. While the enforcement of these patents may have caused problems in the past, they are unlikely to do so in the future. Stephens' patent appears to be a weak one which would be invalidated if it had to withstand litigation. Some commentators have likened the patented technique to distinguishing the right hand from

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<sup>3</sup> PTO examiner interview, pp. 4-5.

<sup>4</sup> Stephens holds patents in the U.S. England, and Australia. He advertises his patented fetal sexing technique in Asian American newspapers in an effort to help women or couples who are interested in having a male child. The women may abort female fetuses. Lowes, R. "Are you stealing from other doctors? Medical procedure and method patents," 73 *Medical Economics*, March 11, 1996, p. 195.



the left hand.<sup>5</sup> Although MHR sparked the ire of the Kansas City Urological Association, which attempted but failed to overturn MHR's patent at the PTO, the MHR patent expired in March 1997. Bogart's patent is on a method that is used in lab testing. It is more akin to a product (e.g., diagnostic test kit) than to a surgical procedure (e.g., scleral incision for cataract surgery) and therefore unlikely to cause as much of a stir. And the strong stance taken by the medical profession in *Pallin v. Singer* has preemptively limited the potential for problems.

However, the problem of medical method patents is insignificant. Medical methods are not easy to patent. They are hard to enforce in terms of monitoring infringement (i.e., lack of easy access to patient records and operating rooms) and in prosecuting infringement (i.e., suing many physicians individually). Because of their personal ethics, many physicians will not patent, or enforce patents on, medical methods.<sup>6</sup> The pace of innovation can be so rapid that a patent can be rendered moot in a short time, if it ever had commercial value in the first place.<sup>7</sup> Also, misappropriating medical inventions by skimming off the "vast pool of unpatented medical knowledge" is unlikely because it carries severe penalties. Certainly the outcome of *Pallin v. Singer* will deter patenting and patent enforcement. The PTO has improved its examination of medical method applications by enhancing in-house expertise and building better access to prior art. Thus, only truly inventive methods, which are novel and nonobvious, will be patented. And as ophthalmologist and patent attorney William Noonan points out, there has been only one case of a physician suing another physician over infringement of a medical method patent.<sup>8</sup> The enforcement ban aside, patenting medical methods will not be a significant problem – certainly nothing like the storm that Dr. Samuel Pallin, the patentholder, created in the ophthalmologic and medical community when he enforced his patent on the chevron incision.

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<sup>5</sup> Neergaard, L. "Move to Patent Surgical Procedures Sparks Fight; Royalties: Doctors Say Controlling the Way They Practice Medicine in Such a Way is Unethical and Drives Up Health Care Costs. They've Persuaded Congress to Consider Outlawing the Practice," *Los Angeles Times*, April 2, 1995, p. 14A.

<sup>6</sup> However, if physicians remained fearful of being potential lawsuit targets, a professional society such as the AMA might compile a list of patented procedures and campaign to invalidate unwarranted patents through reexamination at the PTO.

<sup>7</sup> During the Congressional subcommittee hearing on H.R. 1127, Singer testified that an eye surgery method can be improved in 6-12 months with the free dissemination of knowledge. Hearing, p. 44.

<sup>8</sup> Hearing, p. 72.



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